IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: **NIASPAN ANTITRUST LITIGATION**	**MDL NO. 2460**
THIS DOCUMENT RELATES TO: **ALL ACTIONS**	**MASTER FILE NO. 13-MD-2460**

DuBois, J. **June 2, 2020**

M E M O R A N D U M

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I. INTRODUCTION

This multidistrict litigation involves what has come to be known as a "pay-for-delay," or "reverse payment," settlement—a practice in which a brand-name drug manufacturer brings a patent-infringement action against a generic drug manufacturer and then compensates the generic drug manufacturer for its agreement to delay entering the market with a competing generic version of the brand-name drug. In this case, two putative classes—the Direct-Purchaser Plaintiffs ("DPPs") and the End-Payor Plaintiffs ("EPPs")—aver that the brand-name manufacturer of the drug Niaspan, Kos Pharmaceuticals, Inc. ("Kos"), entered into anticompetitive settlement agreements with the generic manufacturer of that drug, Barr Pharmaceuticals, Inc. ("Barr"), in March of 2005 in order to terminate patent-infringement litigation brought by Kos against Barr in the District Court for the Southern District of New York. Kos was later acquired by defendant AbbVie Inc. ("AbbVie"), and Barr was later acquired by defendant Teva Pharmaceuticals, Inc. ("Teva").

Presently before the Court are End-Payor Plaintiffs' Motion for Class Certification, Defendants' Motion to Exclude the Expert Testimony of Laura Craft and Eric Miller Offered in Support of End-Payor Plaintiffs' Motion for Class Certification, and End-Payor Plaintiffs' Motion to Exclude the Opinions and Testimony of John F. Fritz.

For the reasons that follow, (1) Defendants' Motion to Exclude the Expert Testimony of Laura Craft and Eric Miller is denied, (2) EPPs' Motion for Class Certification is denied without prejudice, and (3) EPPs' Motion to Exclude the Opinions and Testimony of John F. Fritz is denied as moot.

II. BACKGROUND

The background of this case is set forth in detail in the Court's Memorandum and Order of September 5, 2014. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735 (E.D. Pa. 2014). This Memorandum recites only the facts and procedural history relevant to the motions presently before the Court.

Defendant AbbVie, a drug manufacturer that was spun off from Abbott Laboratories ("Abbott") in January 2013, manufactures and sells Niaspan, a brand-name prescription drug, primarily used in the treatment of lipid disorders. In the early 1990s, Kos, acquired by AbbVie in December 2006, developed a therapeutically-effective time-release version of niacin, which does not cause the side effects previously associated with niacin. Kos obtained a series of U.S. patents on time-release niacin and marketed the drug using the trademark Niaspan. Niaspan has been manufactured and sold by AbbVie (and AbbVie's predecessor corporations) since September of 1997.

In October 2001, Barr, acquired by Teva in January 2009, filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking authorization to manufacture and sell a generic equivalent of certain dosages of Niaspan. The ANDA process provides for streamlined FDA approval of a bioequivalent generic version of an FDA-approved brand-name drug. As part of the ANDA process, Barr filed certifications with the FDA stating that its generic drug did not infringe any of the patents covering Niaspan and/or that the patents were invalid or unenforceable.

In March 2002, Kos initiated the first of a series of patent-infringement lawsuits against Barr in the Southern District of New York, alleging infringement of its Niaspan patents. After three years of litigation, on April 12, 2005, Kos and Barr entered into several related settlement

agreements terminating the litigation. These agreements constitute the alleged "pay-for-delay" or "reverse payment" settlement that is the subject of this litigation.

EPPs allege that defendants' conduct violated the antitrust laws of 16 states, the consumer protection laws of 5 states, the unfair trade practices laws of 7 states, and the unjust enrichment laws of 25 states—a total of 53 state laws from 26 jurisdictions. *See* Defs.' Opp'n to EPPs' Mot. for Class Certification ("Defs.' Opp'n Class Cert") 3; Defs.' Apps. State L. Supp. Defs.' Opp'n to EPPs' Mot. for Class Certification (("Defs.' App.") A1-1–A1-4. Specifically, EPPs claim that as a result of the alleged unlawful reverse payment settlement, putative class members "were denied the opportunity to purchase generic Niaspan before September 20, 2013, and were further denied the benefit of the price competition that would have ensued in a competitive environment where Kos launched an authorized generic Niaspan to compete with Barr during the 180-day exclusivity period."[1] Mem. L. Supp. EPPs' Mot. for Class Certification ("EPPs' Mot. Class Cert") 12.

On December 19, 2018, EPPs filed a Motion for Class Certification. In their motion, EPPs seek certification of an overcharges class and an unjust enrichment class, each with two subclasses, a third party payor ("TPP") and a consumer subclass:

- Third Party Payor ("TPP") Overcharges Sub-class Definition:
    - All entities in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin for consumption by their members, employees, insureds, participants, or

[1] "[T]o encourage generic entry and to compensate ANDA filers for the expense and risk of a potential infringement lawsuit, federal law grants the first generic manufacturer to file a[n] . . . ANDA application (i.e., the "first-filer") a 180–day period of exclusive marketing rights." *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 741 (E.D. Pa. 2014). The 180–day period is exclusive only with respect to other ANDA applicants and does not prohibit the holder of an approved New Drug Application (the manufacturer of the brand-name drug) from marketing its own generic version of its drug (an authorized generic). *Id.*

beneficiaries during the period April 3, 2007 through January 31, 2018 (the "Overcharges Class Period").

- Consumer Overcharges Sub-class Definition:
  - All persons in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin for consumption by themselves or their families during the period April 3, 2007 through January 31, 2018 (the "Overcharges Class Period").
- TPP Unjust Enrichment Sub-class Definition:
  - All entities in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Alabama, Arizona, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and Wyoming for consumption by their members, employees, insureds, participants, or beneficiaries during the period April 3, 2007 through September 19, 2013 (the "Unjust Enrichment Class Period").
- Consumer Unjust Enrichment Sub-class Definition:
  - All persons in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Alabama, Arizona, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and Wyoming for consumption by themselves or their families during the period April 3, 2007 through September 19, 2013 (the "Unjust Enrichment Class Period").
- Excluded from Overcharges and Unjust Enrichment Classes:
  - Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
  - All federal or state government entities other than cities, towns or municipalities with self-funded prescription drug plans;
  - All persons or entities who, after September 20, 2013, paid and/or provided reimbursement for branded Niaspan and did not pay and/or provide reimbursement for generic Niaspan;
  - All persons with a tiered co-pay plan who purchased only generic Niaspan;
  - All persons or entities who purchased Niaspan for purposes of resale or directly from Defendants or their affiliates·
  - Fully insured health plans (i.e., plans that purchased insurance from another third party payor covering 100% of the Plan's reimbursement obligations to its members);
  - Pharmacy Benefit Managers ("PBMs");

- Flat co-payers (i.e., consumers who paid the same co-payment amount for brand and generic drugs);
- The judges in this case and any members of their immediate families;
- All Counsel of Record.

End-Payor Plaintiffs' Motion for Class Certification ("EPPs' Mot. Class Cert.") 1–3.[2]

In their motion, EPPs ask the Court to appoint plaintiffs A.F. of L. – A.G.C. Building Trades Welfare Plan, City of Providence, Rhode Island, Electrical Workers 242 and 294 Health & Welfare Fund, International Union of Operating Engineers Local 49 Health and Welfare Fund, International Union of Operating Engineers Local 132 Health and Welfare Fund, New England Electrical Workers Benefits Fund, Painters District Council No. 30 Health & Welfare Fund, United Food & Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund, Miles Wallis, and Carol Prasse (collectively, "named plaintiffs") as class representatives. *Id*. 3. EPPs also request appointment of Kenneth A. Wexler of Wexler Wallace LLP, Steve Shadowen of Hilliard Shadowen LLC, Michael Buchman of Motley Rice LLC, and Marvin Miller of Miller Law LLC as Co-Lead Counsel, and Jeffrey Kodroff of Spector Roseman & Kodroff P.C. as Liaison Counsel for the EPP class pursuant to Fed. R. Civ. P. 23(c)(1)(B) and 23(g). *Id*. 3–4.

On February 25, 2019, defendants responded to EPPs' motion for class certification and filed a motion to exclude the expert testimony of EPP class certification experts Eric Miller and Laura Craft. On March 25, 2019, EPPs filed a reply in support of their motion for class certification, responded to defendants' motion to exclude the expert testimony of Miller and Craft, and filed a motion to exclude the expert testimony of defendants' expert John Fritz. On

[2] At the Hearing on May 14 and 15, 2019, EPPs stated that the class definitions submitted with the Motion for Class Certification contained errors and submitted a slide deck correcting those errors. *See* May 14, 2019 Hr'g Tr. ("May 14 Tr.") 101:23–103:9; EPPs' Slide Deck (ECF No. 660) 51–54. The above class definitions incorporate those corrections.

April 8, 2019, defendants responded to EPPs' motion to exclude Fritz's testimony. The Court held Hearings on EPPs' class certification motion and the related motions to exclude expert testimony on May 14 and 15, 2019, and July 23, 2019.

III. MOTION TO EXCLUDE THE EXPERT TESTIMONY OF LAURA CRAFT AND ERIC MILLER

Defendants argue that the expert testimony of two EPP rebuttal experts on class ascertainability, Eric Miller and Laura Craft, should be excluded under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Mem. L. Supp. Defs.' Mot. Exclude Expert Test. Laura Craft & Eric Miller Offered Supp. EPPs' Mot. Class Certification ("Mem. Exclude Craft & Miller") 1. EPPs oppose defendants' motion and argue that both experts provide admissible evidence. EPPs' Opp'n Defs.' Mot. Exclude Expert Test. Laura Craft & Eric Miller ("Opp'n Mot. Exclude Craft & Miller") 1. For the reasons that follow, the Court agrees with EPPs that Craft and Miller proffer admissible evidence. Defendants' motion to exclude the expert testimony of Craft and Miller is therefore denied.

A. *APPLICABLE LAW*

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

That rule requires the Court to act as a gatekeeper and is applicable to scientific testimony and testimony based on "technical" and "other specialized" knowledge. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). A court must determine whether an expert "employs in

the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

Courts have adopted a "liberal policy of admissibility" with respect to Rule 702. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). As such, the "rejection of expert testimony is the exception and not the rule." *Dorman Prods. v. PACCAR, Inc.*, 201 F. Supp. 3d 663, 686 (E.D. Pa 2016) (DuBois, J.) (quoting Fed. R. Evid. 702 Advisory Committee Note).

Courts must address a "trilogy of restrictions" before permitting the admission of expert testimony: qualification, reliability and fit. *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). The party offering the expert must establish each requirement by a preponderance of the evidence. *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999).

i. Qualification

To qualify as an expert, "Rule 702 requires the witness to have 'specialized knowledge' regarding the area of testimony." *Betterbox Commc'ns Ltd. v. BB Techs., Inc.,* 300 F.3d 325, 335 (3d Cir. 2002). The Third Circuit has instructed courts to interpret the qualification requirement "liberally" and not to insist on a certain kind of degree or background when evaluating the qualifications of an expert. "[T]he Third Circuit noted that a witness can qualify as an expert 'under Rule 702 on the basis of practical experience alone, and a formal degree, title, or educational specialty is not required.'" *Voilas v. Gen. Motors Corp.*, 73 F. Supp. 2d 452, 457 (D.N.J. 1999) (citing *Lauria v. National R.R. Passenger Corp.*, 145 F.3d 593, 599 (3d Cir.1998)).

ii. Reliability

The reliability requirement of *Daubert* "means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 742 (3d Cir. 1994).

iii. Fit

For expert testimony to meet the *Daubert* "fit" requirement, it must "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. "This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591.

B. *DISCUSSION*

The Court reviews defendants' challenges to Miller and Craft's proffered opinions in turn.

i. Eric Miller

In his declaration, Miller proffers two primary conclusions. First, Miller opines that through subpoenas issued to PBMs and pharmacies, EPPs will be able to obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period. Decl. Eric J. Miller ("Miller Decl.") ¶¶ 3, 20. Second, he opines that through the PBM and pharmacy transaction records obtained by the EPPs, the EPPs will be able to identify purchasers of Niaspan and its generic equivalents during the Class Period. *Id*. ¶¶ 8, 10, 20. Miller also states that he "disagrees with [defense expert, Donald] Dietz's suggestion that there is no 'reliable and administratively feasible means to identify class members in this case.'" Miller Decl. ¶ 20.

The Court concludes that Miller meets the Rule 702 requirements, but his testimony is limited to his opinions that (1) EPPs can obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period and (2) EPPs can use PBM and pharmacy transaction records to identify purchasers of Niaspan and its generic equivalents during the class period. To the extent that Miller purports to opine that class members can be identified, he has not addressed the way in which exclusions from the class can be applied and therefore he has not provided reliable grounds for any such opinion.

1. *Qualification*

EPPs claim Miller's "extensive experience obtaining and utilizing comparable data," including his direct involvement with settlement administration in over 25 indirect purchaser pharmaceutical class lawsuits, qualifies him to offer his opinions. Opp'n Mot. Exclude Craft & Miller 15.

Miller attests that he has "personally overseen the methodologies used in indirect purchaser pharmaceutical class actions to identify class members," which "utilized prescription data obtained from the records of pharmacies and PBMs to identify consumers who may be class members." Miller Decl. ¶ 9. He has 18 years of experience administering class actions settlements, including more than 25 indirect purchaser pharmaceutical class cases. Opp'n Mot. Exclude Craft & Miller 2. The Court concludes that Miller is sufficiently qualified to offer his opinions that EPPs can obtain brand and generic Niaspan transaction records for the class period and that those records can be used to identify purchasers of brand and generic Niaspan during the class period.

2. *Reliability*

Defendants argue that Miller is unreliable because he (1) did not offer a methodology to identify class members and (2) did not review any data produced in this case, address the challenges posed by the class definition, or address limitations in data availability and access in PBMs' data systems. Mem. Exclude Craft & Miller 4–9.

EPPs respond that (1) Miller need not provide a methodology to identify class members because he does not purport to provide a method for ascertaining class members, and (2) Miller was not required to review the record because his testimony is reliably based on his past industry experience and his involvement in four cases in which pharmaceutical transaction data was obtained and used. Opp'n Mot. Exclude Craft & Miller 15, 17–18.

First, the Court agrees with EPPs that Miller need not provide a methodology for identifying class members because he does not opine on such a methodology. Though EPPs' evidence of a reliable and administratively feasible methodology for identifying class members is critical to the Court's ascertainability inquiry, Miller's testimony does not address that issue—he only opines on the question whether Niaspan and generic *purchasers* can be identified. As Miller explained during his deposition, his declaration did not consider the EPPs' class definition, did not compare the EPPs' definition to the class definitions in *Relafen*, *Tricor*, *Provigil* and *Fluoride Tablets*, and did not address any of the exclusions in EPPs' class definition. Videotape Dep. Eric Miller 26:13–19, 27:13–18, 30:1–5. For those reasons, Miller will not be permitted to testify that he disagrees with defense expert Donald Dietz's opinion that there is no reliable and administratively feasible means to identify class members.

Second, the Court concludes that Miller has "good grounds" for both of his conclusions. Miller opines that EPPs can obtain brand and generic Niaspan transaction records for the class

period based on his past experience with settlement administration in pharmaceutical cases in which he was involved. Miller Decl. ¶ 10. Specifically, he relies upon his experience in the *Relafen*, *Tricor*, *Provigil* and *Fluoride Tablets* cases, in which pharmaceutical records were obtained through subpoenas to pharmacies and PBMs. *Id*. ¶¶ 10–15. Miller's past experience provides reasonable grounds for him to conclude that subpoenas to PBMs and pharmacies will result in the production of pharmaceutical records in this case. *See In re Paulsboro Derailment Cases*, 746 F. App'x 94, 98 (3d Cir. 2018) (holding that an expert may base his opinion upon personal experience).

Similarly, Miller opines that EPPs can identify purchasers of Niaspan and its generic equivalents during the class period based on his experience with similar subpoenaed data. Miller Decl. ¶ 8. Specifically, he states that in the *Relafen*, *Tricor*, *Provigil* and *Fluoride Tablets* cases, the electronic data fields enabled the plaintiffs to identify each drug purchaser. *Id*. ¶¶ 11–18. Miller's past experience in which the subpoenaed pharmaceutical data identified drug purchasers provides good grounds for his belief that the production of Niaspan pharmaceutical data would enable the identification of brand and generic Niaspan purchasers.

Because Miller has good grounds for his opinions on the identification of purchasers of brand and generic Niaspan, defendants' arguments that Miller failed to review the produced data or to address limitations in data availability and retrieval address the weight of Miller's testimony, not its admissibility. *See In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999) ("[T]he judge should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude the evidence if the flaw is large enough that the expert lacks the "good grounds" for his or her conclusions.").

For all of the forgoing reasons, Miller will be permitted to testify that brand and generic Niaspan purchasers can be identified. He will not be permitted to testify that class members can be identified.

3. *Fit*

Defendants argue that Miller's experience with claims administration in the settlement of cases is inapposite to this case because it does not involve a settlement class. Mem. Exclude Craft & Miller 10–11. In support, they point to the fact that several courts have recognized that "the successful administration of a settlement does not necessarily mean that a litigation class could be ascertained." *Id*. at 10.

EPPs respond that the fact Miller's experience with settlement administration does not impact his opinion on the availability of the data. *See* Opp'n Mot. Exclude Craft & Miller 18–19. They contend Miller's testimony addressing the existence and availability of PBM and pharmacy transaction data is relevant to the identification of brand and generic Niaspan purchasers.

The Court rejects defendants' argument that Miller's testimony is not relevant because his experience is based on settlement claims administration. Although defendants' are correct that "[t]he successful administration of a settlement does not necessarily mean that a litigation class could be ascertained," *In re Wellbutrin XL Antitrust Litig*., 308 F.R.D. 134, 151 n.8 (E.D. Pa. 2015), EPPs correctly state that "the *fact* of data availability is the same, regardless of the context." Opp'n Mot. Exclude Craft & Miller 19. The Court thus concludes that Miller's testimony, as limited *supra*, satisfies the fit requirement under Rule 702.

4. *Conclusion*

Accordingly, that part of defendants' motion seeking to exclude all of the opinions and testimony of Miller is denied. However, Miller's testimony is limited to his opinions that (1) EPPs can obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period and (2) EPPs can use PBM and pharmacy transaction records to identify purchasers of Niaspan and its generic equivalents during the class period. However, he has not provided the required foundation to opine that class members can be identified in a reliable and administratively feasible manner.

ii. Laura Craft

In her declaration, Laura Craft attests that if provided with data from TPPs, PBMs, and pharmacies containing the identities of purchasers of Niaspan and its generic equivalents during the class period, she can compile a list reflecting the identities of the members of the proposed class in a manageable process that "can be carried out programmatically." Decl. Laura R. Craft ("Craft Decl.") ¶ 10. For the reasons below, the Court concludes that Craft's opinion is admissible under Rule 702's "liberal policy of admissibility."

1. *Qualification*

EPPs argue that Craft is qualified as president of data analytics firm OnPoint Analytics, specializes in collecting, manipulating, and analyzing pharmaceutical industry data, especially in the litigation context, and has applied her expertise to over fifty pharmaceutical cases. Opp'n Mot. Exclude Craft & Miller 5–6.

Craft's qualifications include "extensive experience [at OnPoint] working with insurance and claims processing data, including the processing of prescription drug benefits." Craft Decl. ¶ 3. She also has extensive experience using transactional data to "identify[] individual class

members in a variety of contexts . . . [including] identifying transaction dates, types, and costs, the participants in making payment, and eliminating duplicates." *Id.* ¶ 5. Craft declares that OnPoint's expertise with transactional data includes "the cleaning and transformation processes that create consistency and allow efficient programming across data obtained from multiple sources." *Id*.

The Court concludes that Craft's extensive experience working with pharmaceutical data qualifies her to opine that EPP class members can be identified in a programmatic and manageable process.[3]

2. *Reliability*

Defendants contend that Craft's testimony is unreliable because she has not reviewed the data produced in this case and has not offered a methodology for identifying class members. Mem. Exclude Craft & Miller 5–9.

EPPs respond that Craft properly based her opinions on her experience and not on the produced data because "absent a subpoena and a negotiated production process and the execution of protective orders that assure that there is a HIPAA-qualified protective order in place, one would not expect to see samples that would be, standalone, sufficient to answer all of the questions which might be implicit in defining the class." Opp'n Mot. Exclude Craft & Miller 12. They further argue that Craft justifiably relies on sworn declarations by four of the largest PBMs that they maintain their claims data in the industry standard format and that they maintain the

[3] The analysis under *Daubert* involves a preliminary assessment of admissibility and has no effect on the Court's substantive analysis of whether the admissible evidence satisfies the more rigorous Rule 23 ascertainability requirement by a preponderance of the evidence. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. at 144, 151 (concluding that plaintiff's witness was "sufficiently qualified to be an expert" but offered evidence that "[fell] short" of satisfying ascertainability).

types of data that would be required to identify class members and apply key exclusions. *Id*. at 10–12.

EPPs also contend that Craft explained a six-step methodology for identifying class members based on her experience manipulating pharmaceutical data, *id*. at 9, and that her methodology is particularly well-suited for drug sales in the pharmaceutical industry, "which are tracked, monitored, and recorded across a set of substantially uniform variables." Reply Mem. L. Supp. EPPs' Mot. Class Certification ("EPPs' Reply Class Cert.") 6.

The Court concludes that Craft's failure to review the data produced in this case does not render her opinion unreliable. Although Craft does not rely on actual produced data, she relies on her experience working with pharmaceutical data from PBMs, TPPs, drug manufacturers, pharmacies, and consumers. Craft Decl. ¶ 5–6. Craft reports that the data standardization process "is particularly easy in the pharmaceutical industry because the specific types of data reported are already relatively standard" and "[PBM] databases are generally able to report the same key variables." *Id*. She also relies on declarations from PBM representatives Kyle Brua (Prime Therapeutics LLC, March 28, 2018), Jonathan Stocker (Prime Therapeutics LLC, March 28, 2018), Tom Henry (Express Scripts, Inc., March 28, 2018), Robert Lahman (OptumRx, Inc. March 26, 2018), and Steven Schaper (Caremark, LLC, March 20, 2018), which detail the type of data that PBMs retain.

The Court further concludes that Craft's relatively threadbare methodology is adequate under the liberal admissibility standard of Rule 702. In her declaration, Craft asserts that "OnPoint would be able to merge the data from the various sources, identify and eliminate data errors, transform the data to standardize the fields, eliminate duplicates, and compile a list reflecting the identities of the class members contained in the data." Craft Decl. ¶ 10.

Defendants are correct that Craft does not explain how any of these steps would be carried out and "did not describe a specific method" to identify payors who meet the class definitions in this case. Mem. Exclude Craft & Miller 6. However, Craft reviewed the class exclusions, and declared that "OnPoint has extensive experience applying these types of exclusions to pharmaceutical data." Craft Decl. ¶ 9. As such, Craft's opinion that she can create a list of class members and apply the class exclusions in this case is based on her experience applying these types of exclusions to similar data in other cases. The Court determines that Craft's reliance upon her past experience applying "these types of exclusions" provides sufficient grounds for her belief that she can do so again in this instance. Defendants' objections to Craft's assurances that she can apply the class exclusions go to the weight of her testimony and not its admissibility. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

3. *Fit*

Defendants argue that Craft has not shown her experience is sufficiently analogous because "Craft's declaration did not identify a single case that showed she had applied her (unspecified) methodology in a comparable setting." Mem. Exclude Craft & Miller 10. However, as explained above, Craft states that she has "extensive experience applying these types of exclusions to pharmaceutical data." Craft Decl. ¶ 9. Craft's declaration rebuts defense expert Dietz's opinion by explaining that she and OnPoint "routinely perform[] precisely th[e] type of work" that Dietz incorrectly (in her view) identifies as 'difficult' and 'cumbersome.'" Opp'n Mot. Exclude Craft & Miller 8. Thus, Craft's testimony assists the Court in understanding the evidence relating to whether EPPs have provided a reliable and

administratively feasible mechanism for identifying class members, which is relevant to the Court's determination of class ascertainability.

4. *Conclusion*

The Court thus concludes that Craft's expert opinion is admissible. That part of defendants' motion seeking to exclude the opinion and testimony of Laura Craft is denied.

IV. EPPS' MOTION FOR CLASS CERTIFICATION

A. *LEGAL STANDARD*

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 248 (3d Cir. 2016). Subsection (a) of Federal Rule of Civil Procedure 23 sets out four prerequisites for a class action—numerosity, commonality, typicality, and adequacy. Subsection (b) provides additional requirements for each type of class action. To obtain certification under Rule 23(b)(3), as EPPs seek to do in this case, the moving party must also show "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." These requirements are referred to, respectively, as predominance and superiority. Rule 23(b)(3) also contains an implied, judicially-created requirement that the identities of class members are ascertainable. *Byrd v. Aaron's Inc.*, 784 F.3d 154, 162 n.5 (3d Cir. 2015).

"The party seeking certification bears the burden of establishing each element of Rule 23." *In re Modafinil Antitrust Litig.*, 837 F.3d at 248. "[T]rial courts 'must engage in a rigorous analysis and find each of Rule 23[ ]'s requirements met by a preponderance of the evidence before granting certification.' They must do so even if it involves judging credibility, weighing

evidence, or deciding issues that overlap with the merits of a plaintiff's claims." *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 304 (3d Cir. 2016) (citing *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 316–25 (3d Cir. 2008)). The Rule 23 analysis also requires courts to "determine the nature of the evidence, and how plaintiffs would present this evidence at trial." *In re Domestic Drywall Antitrust Litig.*, 322 F.R.D. at 221. However, "a court should not address merits-related issues 'beyond what is necessary to determine preliminarily whether certain elements will necessitate individual or common proof.'" *Harnish*, 833 F.3d at 305.

The Third Circuit has "repeatedly emphasize[d] that [a]ctual, not presumed conformance with Rule 23 requirements is essential." *Gonzalez v. Corning*, 885 F.3d 186, 192 (3d Cir. 2018) (internal quotations omitted). "When courts harbor doubt as to whether a plaintiff has carried her burden under Rule 23, the class should not be certified." *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 483 (3d Cir. 2018).

B. *DISCUSSION*

EPPs contend that they meet the four requirements under Rule 23(a) and the three requirements under Rule 23(b)(3). The Court addresses each such requirement in turn.

C. *RULE 23(A) REQUIREMENTS*

EPPs must initially satisfy the four prerequisites detailed in Rule 23(a): numerosity, commonality, typicality, and adequacy. The Court concludes that each requirement is satisfied.

i. Numerosity

Rule 23(a)(1) requires that the class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1).

EPPs assert that "Niaspan prescriptions peaked at nearly 600,000 per month in 2011," and argue that joinder is impracticable for such a large class. Mem. L. Supp. EPPs' Mot. Class

Certification ("EPPs' Class Cert. Mem.") 8. The Court agrees with EPPs and concludes that the numerosity requirement is satisfied.

ii. Commonality

To satisfy Rule 23(a)(2), there must be "questions of law or fact common to the class." Satisfaction of the commonality requirement requires that plaintiffs demonstrate that their claims "depend upon a common contention," the resolution of which "will resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal–Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). "Commonality does not require an identity of claims or facts among class members; instead, [t]he commonality requirement will be satisfied if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class." *Johnston v. HBO Film Mgmt., Inc*., 265 F.3d 178, 184 (3d Cir. 2011).

The Court agrees with EPPs that most of the "central questions in this case focus entirely on Defendants' conduct" and involve common questions. EPPs' Class Cert. Mem. 9. These common questions include, *inter alia*, (1) whether Kos entered into a contract, combination, and/or conspiracy with Barr to restrain trade; (2) whether Kos paid cash and/or other valuable consideration to Barr in exchange for a promise to delay the launch of generic Niaspan; (3) whether defendants had pro-competitive justifications for their conduct; and (4) whether defendants possessed market power in the relevant market. The commonality requirement is satisfied.

iii. Typicality

Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." The Third Circuit has a "low threshold" for satisfying typicality. *See In re Nat'l Football League Players Concussion Injury Litig*., 821 F.3d 410, 428 (3d Cir. 2016). To conduct the typicality inquiry, the Court must examine "whether the named plaintiffs' claims are typical, in common-sense terms, of the class, thus suggesting that the

incentives of the plaintiffs are aligned with those of the class." *In re Blood Reagents Antitrust Litig.*, No. 09-2081, 2015 WL 6123211, at *26 (E.D. Pa. Oct. 19, 2015) (DuBois, J.).

EPPs argue that typicality is satisfied because "named Plaintiffs' claims arise out of the same facts and legal theories that give rise to the claims of all EPP Class members: Kos and Barr entered into a reverse-payment settlement that unlawfully extended Kos' monopoly over the Niaspan market and delayed the onset of generic competition." EPPs' Class Cert. Mem. 11. Defendants do not contest that EPPs have satisfied the typicality requirement. The Court concludes that the typicality requirement is satisfied.

iv. Adequacy

Rule 23(a)(4) requires plaintiffs to show that "the representative parties will fairly and adequately protect the interests of the class." "Whether adequacy has been satisfied 'depends on two factors: (a) the plaintiff's attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class.'" *McDonough v. Toys R Us, Inc.*, 638 F. Supp. 2d 461, 477 (E.D. Pa. 2009). "Only a fundamental conflict will defeat adequacy of representation." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 223 (3d Cir. 2012), *judgment vacated on other grounds*, 570 U.S. 913 (2013).

EPPs contend that "plaintiffs are represented by experienced counsel thoroughly familiar with litigating complex class actions" and "there is no likelihood of a conflict of interest among class members." EPPs' Class Cert. Mem. 11–12. Defendants make no argument to the contrary, and the Court agrees with EPPs that the adequacy requirement is satisfied.

D. *RULE 23(B)(3) REQUIREMENTS*

EPPs must also satisfy the predominance and superiority requirements of Rule 23(b)(3) and the ascertainability requirement. *See In re: Domestic Drywall Antitrust Litig.*, 322 F.R.D.

188, 200 (E.D. Pa. 2017). Defendants argue that EPPs fail their burden of proving each of these requirements. The Court addresses each such requirement in turn, beginning with ascertainability.

i. Ascertainability

The ascertainability "inquiry is two–fold, requiring a plaintiff to show that: (1) the class is 'defined with reference to objective criteria'; and (2) there is 'a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.'" *Byrd v. Aaron's Inc*., 784 F.3d 154, 163 (3d Cir. 2015). "Plaintiff has the burden of making this showing by a preponderance of the evidence, and the district court must 'undertake a rigorous analysis of the evidence to determine if the standard is met.'" *City Select Auto Sales Inc. v. BMW Bank of N. Am. Inc*., 867 F.3d 434, 439 (3d Cir. 2017) (internal citations omitted). "However, plaintiff need not 'be able to identify all class members at class certification—instead, a plaintiff need only show that 'class members can be identified.'" *Id.* (internal citations omitted).

The Third Circuit has articulated three principal rationales for the ascertainability standard:

> First, ascertainability and a clear class definition allow potential class members to identify themselves for purposes of opting out of a class. Second, it ensures that a defendant's rights are protected by the class action mechanism, and that those persons who will be bound by the final judgment are clearly identifiable. Finally, it ensures that the parties can identify class members in a manner consistent with the efficiencies of a class action.

City Select Auto Sales Inc., 867 F.3d at 439 (internal quotations and citations omitted).

"The predominance and ascertainability inquiries are distinct . . . because the ascertainability requirement focuses on whether individuals fitting the class definition may be identified without resort[ing] to mini-trials, whereas the predominance requirement focuses on

whether essential elements of the class's claims can be proven at trial with common, as opposed to individualized, evidence." *Byrd*, 784 F.3d at 164.

EPPs argue that under the governing Third Circuit law, plaintiffs can satisfy ascertainability with "almost zero evidence." EPPs' Class Cert. Mem. 17. In support, EPPs rely heavily on *Byrd*, for the proposition that EPPs need not show "how the records would be obtained, who would obtain them, or who would do the matching of records." EPPs' Class Cert. Mem. 18.

Defendants' respond that EPPs "offer a gross misreading of *Byrd* and the Third Circuit's ascertainability jurisprudence." Defs.' Opp'n Class Cert. 37.

The Court agrees with defendants that EPPs mischaracterize the Third Circuit ascertainability standard. Contrary to EPPs' assertion, *Byrd* does not stand for the proposition that ascertainability requires less than a rigorous showing of administrative feasibility. In *Byrd*, the Third Circuit reversed a denial of class certification in a case in which the district court "summarily adopted the Magistrate Judge's Report and Recommendation, and no oral argument was held on the class-certification motion," notwithstanding the fact that the plaintiffs had filed an objection to the Report and Recommendation that addressed class ascertainability. *Byrd*, 784 F.3d at 169–170. As such, the Third Circuit ruled that the district court erred in failing to conduct a rigorous analysis of the evidence presented.

Although Judge Rendell filed a concurring opinion in *Byrd* in which she opined that "the time has come to do away with [the ascertainability requirement]," that position has not been adopted by this Circuit. *See Byrd*, 784 F.3d at 172 (Rendell, J., concurring). As the Third Circuit recently reiterated, plaintiffs have the burden of showing ascertainability "by a preponderance of the evidence, and the district court must 'undertake a rigorous analysis of the

evidence to determine if the standard is met.'" *City Select Auto Sales Inc.*, 867 F.3d at 439. Courts in this district have consistently rejected EPPs' argument that *Byrd* lowered the Third Circuit ascertainability standard, and this Court agrees with those decisions. *See, e.g.*, *In re Domestic Drywall Antitrust Litig.*, No. 13-2437, 2017 WL 3700999, at *8 (E.D. Pa. Aug. 24, 2017) ("[In *City Select*,] the court reaffirmed its prior precedent and did not take the opportunity to retreat from the "heightened" ascertainability standard that has been developed in this Circuit, as urged by Judge Rendell in her *Byrd* concurrence."); *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *11 (E.D. Pa. June 10, 2015) ("[P]lans to create a methodology at a later date do not satisfy the rigorous analysis insisted upon by the Third Circuit and I do not read *Byrd* to alter these requirements.").

Thus, the Court will rigorously analyze EPPs' evidence of ascertainability. While EPPs need only show at class certification that class members can be identified, *City Select*, 867 F.3d at 439, "actual, not presumed[,] conformance with [the ascertainability] requirement[] is essential." *Gonzalez v. Corning*, 885 F.3d 186, 192 (3d Cir. 2018) (internal quotations and alterations omitted). The Court next considers whether EPPs' class definition is defined with objective criteria.

1. *Defining Class with Reference to Objective Criteria*

EPPs argue that the provided class definitions are defined with reference to objective criteria. EPPs' Class Cert. Mem. 13. Defendants disagree, arguing that "given the complex flow of payments and reimbursements in the pharmaceutical distribution chain, it is far from clear exactly who is in the class and who is not." Defs.' Opp'n Class Cert. 29. Defendants also claim that there is an ambiguity in the class definition regarding whether a payor includes any entity that bears risk for drug costs. *Id.* at 29–31.

EPPs respond that "[t]he ambiguities that Defendants assert do not appear on the face of the class definitions, which is the standard by which to determine class membership." EPPs' Reply Class Cert. 3.

The Court agrees with EPPs that the class definition is defined with reference to objective criteria and satisfies the first prong of the ascertainability analysis. Defendants' arguments do not challenge the objective nature of the class criteria. *Cf. City Select Auto Sales Inc.*, 867 F.3d at 439 ("Under the objective criteria requirement, '[a] class definition that depends on subjective criteria, such as class members' state of mind, will fail for lack of definiteness.'"). The Court next turns to the evidence submitted by EPPs to establish that they have a reliable and administratively feasible mechanism for identifying class members.

2. *Reliable and Administratively Feasible Mechanism for Determining Whether Putative Class Members Fall Within the Class Definition*

EPPs assert that they have "submitted evidence that an administratively feasible methodology exists to allow for the determination of whether a TPP or consumer falls within the definitions of the Proposed Classes." EPPs' Class Cert. Mem. 14. Defendants respond that EPPs have not met their burden of proving a reliable and administratively feasible methodology by a preponderance of the evidence. Defs.' Opp'n Class Cert. 34.

Upon a rigorous analysis of the evidence, the Court determines that EPPs have failed to carry their burden of showing a reliable and administratively feasible mechanism for identifying class members by a preponderance of the evidence.

a. EPPs' Evidence of a Reliable and Administratively Feasible Mechanism

EPPs face an uphill battle in carrying their burden of proving they have a reliable and administratively feasible mechanism for identifying class members. Courts in this district have

held in similar pay-for-delay cases that end-payor plaintiffs have failed to provide adequate evidence of an administratively feasible mechanism for identifying class members. *See, e.g.*, *Vista Healthplan, Inc. v. Cephalon, Inc*., No. 06-1833, 2015 WL 4737288, at *11 (E.D. Pa. Aug. 4, 2015) ("Plaintiffs have . . . not met their burden of establishing that any methodology for identifying class members would be administratively feasible."); *see also In re Wellbutrin XL Antitrust Litig*., 308 F.R.D. 134, 149–50 (E.D. Pa. 2015) ("[Plaintiffs ha[ve] not shown by a preponderance of the evidence that there is a reliable and administratively feasible mechanism for determining which PBMs and individual consumers are members of the class.").

EPPs argue in this case, they "have provided the [evidentiary] record that the courts in *Wellbutrin* and *Vista* [Healthplan] lacked." EPPs' Reply Class Cert. 3. They argue that their evidence demonstrates "that obtaining, standardizing, and merging data from multiple sources with the goal of ascertaining class members is . . . common practice in antitrust litigation, [and] is especially well-suited to the pharmaceutical industry." EPPs' Reply Class Cert. 4. The Court reviews EPPs' evidence below.

First, EPPs proffer evidence that the relevant pharmaceutical transaction data exists. EPPs' expert, Myron Winkelman, asserts that "[e]very prescription drug transaction in the United States is well-documented and records of those transactions are maintained so that TPPs and consumers can identify, at a minimum, the prescriptions drugs they purchased, the date on which they were purchased, and the price they each paid for the medication." Decl. Myron Winkelman ("Winkelman Decl.") ¶ 18. Winkelman also claims that "PBMs are obligated by their contractual agreements with the TPPs to maintain records in connection to the processing, payment and denial of claims," *id*. ¶ 35, and "mail order and retail pharmacies maintain extensive records of each consumer's prescription purchase." *Id*. ¶ 36. Finally, Winkelman

opines that pharmaceutical data is "maintained in standardized accepted industry format." *Id.* ¶ 32.

In support of EPPs' claim that the data exists, they have presented short declarations by several PBM representatives. For example, Jonathan Stocker, Vice President of PBM Operations at Prime Therapeutics LLC, declared "Prime has readily accessible records, in an industry standard format created by the National Council for Prescription Drug Program, by which third party payors and consumer can be identified on every purchase of Niaspan and Generic Niaspan that Prime adjudicates on behalf of its third-party payor clients." Decl. Non-Party Prime Therapeutics LLC ("Stocker Decl.") ¶ 7. Similarly, Robert Lahman, Senior Vice President of Industry Relations at Optum Rx, Inc., attested that "OptumRx has readily accessible records, in an industry standard format created by the National Council for Prescription Drug Program, by which third party payors and consumers can be identified on every purchase of Niaspan and Generic Niaspan that OptumRx adjudicates on behalf of its third-party payor clients." Decl. Non-Party OptumRx ("Lahman Decl.") ¶ 5. Both PBM declarants stated that they maintain the records of transaction details in its regular course of business. Stocker Decl. 9; Lahman Decl. ¶ 7.

Second, EPPs proffer evidence that the data is obtainable. They rely on Miller's expert opinions, discussed above, in which Miller states that through subpoenas issued to PBMs and pharmacies, EPPs will be able to obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period, which will enable EPPs to identify purchasers of Niaspan and its generic equivalents during the class period. Miller Decl. ¶¶ 3, 8, 10, 20. As set forth in greater detail above, Miller bases his opinions on his experience in claims administration for settlement classes.

Third, EPPs assert that identifying class members from the obtained pharmaceutical data is administratively feasible. In support, they rely on Craft's declaration, discussed above, in which she states that she can compile a list reflecting the identities of the members of the proposed class in a manageable process that "can be carried out programmatically" and that she has "extensive experience applying these types of exclusions to pharmaceutical data." Craft Decl. ¶¶ 9–10.

EPPs also present a declaration by EPP Interim Co-Lead Counsel, Kenneth Wexler, which synthesizes EPPs' "evidence that an administratively feasible methodology exists to allow for the determination of whether a TPP or consumer falls within the definitions of the Proposed EPP Classes." EPPs' Class Cert. Mem. 14. First, Wexler states that Winkelman has provided evidence that "PBMs, TPPs, pharmacies, and individual consumers have records reflecting what TPPs and consumers purchased Niaspan or its generic versions during the class periods." Decl. Kenneth A. Wexler Supp. EPPs' Mot. for Class Certification ("Wexler Decl.") ¶ 26. Second, Wexler says that EPPs would serve HIPAA-compliant court-issued subpoenas to "the top six Pharmacy Benefit Managers (in terms of market share), the ten largest Third-Party Payors, the top ten chain store pharmacies, and the top five mail order pharmacies" for the production of purchase records for brand and generic Niaspan during the class period. *Id*. ¶¶ 27–28. Third, he says EPPs would retain OnPoint Analytics, transfer the obtained records to OnPoint, which "could then process the data and identify those persons and entities in the data who fit the class definitions." *Id*. ¶¶ 29–30. Finally, Wexler states that the remainder of unidentified class members can obtain records of their relevant purchases and prove their class membership. *Id.* ¶ 31.

Defendants argue that EPPs' evidence does not show that the class is ascertainable, and EPPs' "offer only vague assurances that they will somehow be able to ascertain class members in the future." Defs.' Opp'n Class Cert. 32. They claim that EPPs failed to present a methodology "specific to this case" or provide "evidentiary support that the method will be successful." *Id*. at 33 (citing *Carrera v. Bayer Corp*., 727 F.3d 300, 306, 310 (3d Cir. 2013)). Defendants also raise specific challenges to EPPs' evidence that they can obtain the necessary data and identify class members using pharmaceutical data.

For the reasons below, the Court agrees with defendants that EPPs have not satisfied their burden of proving a reliable and administratively feasible mechanism for identifying class members.

b. Data Obtainability

Defendants contend that EPPs have not shown that the records necessary to identify class members are obtainable and raise several challenges to EPPs' evidence. Defs.' Opp'n Class Cert. 39. Defendants note that EPPs have faced difficulties obtaining data in this case, as evidenced by the fact that when EPPs served deposition and document subpoenas on four PBMs, three PBMs served formal objections, and only two PBMs produced requested data—one of which produced an extremely limited report relating only to the transactions involving named plaintiff AF of L. *Id*. at 22. According to defendants, EPPs' declarations from the PBM representatives are inadequate because they "merely describe in non-specific terms the type of information generated in the claim adjudication process." *Id*. at 20.

Defendants' also challenge Miller's opinion that data of brand and generic Niaspan purchases can be feasibly obtained. They highlight that Miller did not account for data limitations that arose in past cases in which he was involved. Specifically, defendants present

affidavits originally filed in *Relafen*, one of the four cases upon which Miller primarily relies in his report, in which two PBMs, Express Scripts and Medco, attested to the difficulties of data retrieval. *Id.* at 20–21.

EPPs' reply that defendants' objections to data obtainability rely on "outdated" declarations from PBMs and that PBMs' reluctance to produce data "merely underscores the importance of implementing a HIPAA-compliant protective order (which has been done in this case) and, if necessary, the routine matter of enforcing subpoenas." EPPs' Reply Class Cert. 14–15. EPPs also note that "[m]ost of the named Plaintiffs in this litigation were able to provide data for the complete set of relevant transactions going back to around the beginning of the class period." *Id.* at 14.

The Court concludes that, notwithstanding defendants' objections, EPPs have demonstrated by a preponderance of the evidence that the necessary records of brand and generic Niaspan purchases can be obtained. In addition to EPPs' evidence above, the Court notes that the Vice President of Knowledge Solutions and Chief Data Officer for PBM Express Scripts submitted a declaration in this case that "Express Scripts maintains records of claims that can be provided to its Clients, although certain additional fees, costs, or expenses may be associated with this service." Decl. Non-Party Express Scripts, Inc. ("Henry Decl."). Although the failure of several PBMs to provide any record evidence "heightens the Court's concern that such pharmaceutical records may not be obtainable for use in the ascertainability inquiry," *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 150 (E.D. Pa. 2015), the Court is satisfied that through Court-issued subpoenas, records of brand and generic Niaspan transactions can be obtained. However, the Court is concerned about the economic feasibility of obtaining such

information and the ability of EPPs to identify class members in a reliable and administratively feasible manner, issues that the Court addresses below.

c. Methodology for Determining Class Membership

In this case, EPPs have proffered a complex class definition with multiple exclusions. As such, the inquiry as to the ascertainability of class members does not end merely by noting the existence of obtainable records of brand and generic Niaspan purchasers. EPPs "must also demonstrate an administratively feasible method for [applying the exclusions], as required by the class definition." *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *21 (D.N.J. Oct. 30, 2018); *see also City Select*, 867 F.3d at 441–442 (remanding for an inquiry as to whether plaintiffs could use existing database as part of a reliable and administratively feasible means to determine class membership); *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 4737288, at *2 (E.D. Pa. Aug. 4, 2015) ("However, by choosing to define its class with eight specific exclusions, Plaintiffs have created the need for a structured, multi-stepped, individualized fact-finding process in order to determine which individuals would fall within the class definition and which would fall within one of the eight exclusions.").

Defendants contend that EPPs' "experts have affirmatively conceded that they have no methodology for determining class membership in this case." Defs.' Opp'n Class Cert. 1. They assert EPPs failed to provide a feasible methodology for identifying and removing brand and generic Niaspan purchases that fall within class exclusions. *Id*. at 41. Defendants specifically argue that EPPs failed to provide any method for identifying the exclusions of brand-only payors after actual generic entry, generic-only payors on tiered plans, consumers with the same co-

payment for brand and generic drugs, fully insured plans, and state and federal agencies with self-funded prescription drug plans. *Id*. at 41–46.

EPPs respond that Craft proffers a six-step methodology for identifying class members based on her experience manipulating pharmaceutical data, and that her methodology is particularly well-suited for the pharmaceutical industry, "which are tracked, monitored, and recorded across a set of substantially uniform variables." EPPs' Reply Class Cert. 6. EPPs also argue defendants' challenges to feasibility address "tiny subgroups of consumers" and "each argument can be addressed reliably and programmatically through Plaintiffs' proposed methodology." *Id*. at 20.

The Court agrees with defendants on this issue. It is not persuaded that EPPs have an administratively feasible mechanism for identifying class members which involves applying all class exclusions. Craft's six-step methodology that "OnPoint would be able to merge the data from the various sources, identify and eliminate data errors, transform the data to standardize the fields, eliminate duplicates, and compile a list reflecting the identities of the class members contained in the data," Craft Decl. ¶ 10, does not offer a methodology "specific to this case." *See Carrera*, 727 F.3d at 306, 311. Without more information about the process through which Craft claims she will "compile a list reflecting the identities of the class members," defendants lack the ability to meaningfully test the reliability of EPPs' proposed method of identifying class members. *See Carrera*, 727 F.3d at 307. As defendants persuasively stated at oral argument, EPPs have the burden "to develop the methodology and bring it to the Court . . . for [defendants] to be able to evaluate and . . . to present [to the Court any] opposing positions." July 23, 2019 Hr'g Tr. ("July 23 Tr.") 137:5–10.

Craft's expert report assures the Court that she can "programmatically" through a "manageable process" identify a list of class members based on the fact that she has "extensive experience applying these types of exclusions." While Craft's report constitutes admissible evidence, the Court does not find that her report establishes by a preponderance of the evidence that EPPs have an administratively feasible methodology for identifying class members. The Court is particularly concerned by Craft's failure to provide any explanation as to how she can apply all of the exclusions required by plaintiffs' complex class definition in an administratively feasible manner. Mere assurances that a model will be effective to ascertain class members is insufficient. *Carrera*, 727 F.3d at 311–312. Accordingly, plaintiffs must provide more than Craft's *ipse dixit* to prevail under a rigorous ascertainability analysis.[4]

A review of EPPs' evidence belies their claim that all exclusions can be "addressed reliably and programmatically through Plaintiffs' proposed methodology." EPPs' Reply Class Cert. 20. EPPs submitted numerous short declarations that omitted critical supporting details necessary to satisfy the Court. EPPs present an individualized, *ad hoc* approach that does not adequately establish a feasible methodology to address the many class exclusions.

For example, defendants argue that EPPs have proposed no methodology for identifying federal and state entities with self-funded plans—one of the many class exclusions. Defs.' Opp'n Class Cert. 45; May 14 Tr. 175:23–177:15. EPPs respond that federal and government agencies are facially obvious. EPPs' Reply Class Cert. 17. However, defendants provided evidence that such plans are not necessarily facially obvious. May 14 Tr. 176:7–177:6.

[4] EPPs provided the Court with notice of the decision in *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, No. 18-md-2819, (E.D.N.Y. May 5, 2020), in which Judge Gershon of the Eastern District of New York certified an end payor class, relying in part on evidence provided by Craft (Document No. 706, filed May 15, 2020). The Court concludes that this precedent is unpersuasive because the Second Circuit applies a less rigorous standard for analyzing ascertainability.

Moreover, even if such plans were facially obvious, EPPs have not explained how they intend to programmatically apply that exclusion to a putative class estimated at over 600,000 members.

The District of Rhode Island's recent decision on the ascertainability of TPPs is not persuasive on this issue. *See In re Loestrin 24 FE Antitrust Litig.*, No. 1:13-md-2472, 2019 WL 5406077 (D.R.I. Sept. 17, 2019) (Smith, J.). The *Loestrin* court approved of end payor plaintiffs' proposed methodology for identifying class members in part by dismissing concerns regarding the exclusion of federal and state entities with self-funded plans. *Id.* at *30. However, EPPs in that case made specific assurances that self-funded government plans would be removed from the data by PBMs rather than merely identified by name. *Id.* As discussed above, EPPs in this case have only said that such plans would be facially obvious—a contention that defendants have rebutted.

Additionally, defendants contend that plaintiffs have no methodology to identify and exclude "[f]ully insured plans (i.e. plans that purchased insurance from another third party covering 100% of the Plan's reimbursement obligations to its members)." Defs.' Opp'n Class Cert. 44. In her deposition, Craft asserted for the first time that Form 5500s, an IRS form filed by health benefit plans, could be used to identify fully insured plans. *Id*. at 44–45. However, defendants identify inconsistencies on the Form 5500 of named plaintiff AF of L as exemplary of the difficulties in ascertaining fully insured health plans in that manner. *Id*. at 45.

EPPs respond that defendants can only point to "a single Form 5500," which they contend does not rebut Craft's deposition testimony. EPPs' Reply Class Cert. 18. They also note that Winkelman testified that PBMs typically maintain data that can be used to identify and exclude fully-insured plans. *Id*. However, Winkelman acknowledged that no such data has been produced in this case. Defs.' Opp'n Class Cert. 45. In their Reply, EPPs proffer that "even to

the extent that Form 5500 and PBM records do not capture the funding status of a small number of plans, those plans can be presumed to be fully-insured (and thus excluded from the subclasses) unless they are able to supply proof of their self-insured status." EPPs' Reply Class Cert. 19. It is possible that such a methodology, if adopted, could address this challenge. However, the above exchange further illustrates the extent of EPPs' *ad hoc* approach to applying class exclusions and the lack of a comprehensive methodology for systematically applying exclusions in this case.

For some exclusions, EPPs have simply not provided the Court with satisfactory evidence that the exclusions can be systematically applied. For example, the class definition excludes consumers with the same co-payment for brand and generic drugs ("flat co-payors"). Exclusion of these flat co-payers requires a determination of what purchasers would have paid for their brand Niaspan prescription as well as what they would have paid for generic Niaspan they never purchased, a task further complicated by the fact that a health plan co-payment structure can change over time. Defs.' Opp'n Class Cert. 42. EPPs provide evidence that at least some PBMs maintain this information. Jonathan Stocker of Prime Therapeutics stated that "Prime's database houses member plan design details, including, but not limited to, information regarding copayment structure (*i.e.* flat co-payment or percentage co-payment), to the extent applicable." Stocker Decl. ¶ 10. Kyle Brua, also of Prime Therapeutics, declared that "Prime can . . . provide purchase records that exclude purchases made by members with a flat co-payment benefit plan." Decl. Non-Party Prime Therapeutics LLC ("Brua Decl.") ¶ 6. However, as defendants' ascertainability expert, Donald Dietz, explains, in the pharmaceutical industry, the term "flat co-pay" refers to "a co-pay that is set in dollar amounts, as opposed to a percentage of the drug cost . . . and not a single-tier plan design that has the same co-pay for brand and generic drugs."

Expert Rep. Donald J. Dietz ("Dietz Rep.") ¶ 68. Based on the evidence before the Court, EPPs' have not established that PBMs can provide purchase records that exclude consumers with the same co-payment for brand and generic drugs, or that transactional records stored by PBMs and other record holders contain information related to plan details in a way that could be programmatically and feasibly applied in order to exclude "flat co-payors" from the class.

The Court is further concerned about the possibility that even if identification of class members is technically possible, EPPs' proposed methodology would be prohibitively expensive and thus infeasible. At oral argument, EPPs claimed that an administratively feasible mechanism for identifying class members is not required for facilitating the best class notice practicable pursuant to Rule 23(c)(2).[5] *See* May 15, 2019 Hr'g Tr. ("May 15 Tr.") 44:15–46:3. Moreover, EPPs predicted that they may never have to utilize their methodology for identifying class members. *Id.* at 45:8-21. In fact, counsel for EPPs reported that in a similar pay-for-delay case before Judge Saris,[6] when plaintiffs sought to subpoena the relevant pharmaceutical records, they learned it would cost $18 million to obtain the requested information. July 23 Tr. 181:20–182:1. In that case, Judge Saris rejected that approach as "too expensive because it [would] come[] out of the class's recovery," and pursued publication notice instead. *Id*. at 181:20–182–14. In view of these statements, the Court is concerned that EPPs' claimed ascertainability methodology is not reasonably practicable.

The Court harbors significant doubt as to whether EPPs have met their burden of showing

[5] The Court notes that EPPs' interpretation of the ascertainability requirement is not supported by Third Circuit precedent. *See, e.g.*, *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593 (3d Cir. 2012) ("[The ascertainability requirement] protects absent class members by facilitating the 'best notice practicable' under Rule 23(c)(2) in a Rule 23(b)(3) action."); *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013) ("First, at the commencement of a class action, ascertainability and a clear class definition allow potential class members to identify themselves for purposes of opting out of a class.").

[6] Judge, former Chief Judge, U.S. District Court for the District of Massachusetts. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, No. 01-12257, (D. Mass. filed Dec. 19, 2001).

they can identify class members through a reliable and administratively feasible mechanism. "When courts harbor doubt as to whether a plaintiff has carried her burden under Rule 23, the class should not be certified." *Mielo v. Steak 'n Shake Operations, Inc*., 897 F.3d 467, 483 (3d Cir. 2018). Accordingly, the Court declines to certify the EPP class as ascertainable on the state of the present record. As detailed below, the EPP proposed class also fails the predominance and superiority requirements of Rule 23(b)(3).

ii. Predominance

Rule 23(b)(3) requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members." "Rule 23(b)(3), however, does *not* require a plaintiff seeking class certification to prove that each 'elemen[t] of [her] claim [is] susceptible to classwide proof.' What the rule does require is that common questions '*predominate* over any questions affecting only individual [class] members.'" *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 568 U.S. 455, 469 (2013) (emphasis in original).

"An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016) (internal quotations and citations omitted).

"The aim of the predominance inquiry is to test whether any dissimilarity among the claims of class members can be dealt with in a manner that is not 'inefficient or unfair.'" *In re Asacol Antitrust Litig*., 907 F.3d 42, 51 (1st Cir. 2018). "Inefficiency can be pictured as a line of thousands of class members waiting their turn to offer testimony and evidence on individual issues." *Id*. "Unfairness is equally well pictured as an attempt to eliminate inefficiency by

presuming to do away with the rights a party would customarily have to raise plausible individual challenges on those issues." *Id*. at 51–52.

EPPs' argue that common issues predominate across their antitrust claims and unjust enrichment claims, and that aggregate damages can be calculated on a classwide basis. EPPs' Class Cert. Mem. 20–28. Specifically, EPPs claim they will be able to prove their antitrust claims with common evidence that there was an unlawful restraint of trade through an unjustified reverse payment from Kos to Barr, that the reverse payment had anticompetitive effects in the relevant market, that the anticompetitive effects outweighed any pro-competitive justifications, and that EPPs sustained class-wide impact, or injury, caused by defendants' actions. *Id*. at 20–25. They also assert that their unjust enrichment claims can be proven by the same common evidence used to prove that unlawful delay in generic entry produced monopoly profits at the expense of EPPs. *Id*. at 26; EPPs' Reply Class Cert. 65.

Defendants respond that individual questions predominate because EPPs lack common evidence of antitrust injury and cannot establish that class members were injured without resorting to individualized evidence that would overwhelm common questions. They argue that EPPs improperly apply the federal overcharge standard for antitrust injury, but even under that injury standard, EPPs have no common proof of antitrust injury.[7] They further contend that EPPs' evidence of classwide injury relies on averages that impermissibly conceal uninjured class members and identify specific subsets of the class that are potentially uninjured. Defendants also raise challenges to EPPs' aggregate damages model, and contend that many state antitrust laws, unjust enrichment laws, and unfair trade practices and consumer protection laws require proof of

[7] Under federal antitrust law, antitrust injury occurs the moment that a purchaser incurs an overcharge. *See Adams v. Mills*, 286 U.S. 397, 407 (1932). Antitrust injury is also referred to as "antitrust impact." *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 311.

actual damages and that variations between the state laws raise individualized questions that overwhelm the common issues.

The Court considers each of defendants' challenges in turn.

1. *The Impact of Individual Questions for Antitrust Injury and Impact*

EPPs argue that defendants' predominance challenges focus on proof of injury, and that common questions predominate based on EPPs' "common proof to establish the [other] essential substantive elements of their antitrust claims, including the presence of a 'large, unjustified reverse-payment,' market power, anti competitive effects, and causation." EPPs' Reply Class Cert. 30.

The Court rejects EPPs' argument on this issue. It is well established that the lack of common evidence of antitrust injury or impact alone can cause individual questions to predominate. *See, e.g.*, *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 262 (3d Cir. 2016) ("In an antitrust class action, 'impact often is critically important for the purpose of evaluating Rule 23(b)(3)'s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof.'").

2. *Antitrust Injury and Impact Standard for State Law Claims*

It is undisputed that under longstanding federal antitrust law, antitrust injury occurs the moment that a purchaser incurs an overcharge. *See e.g., Adams v. Mills*, 286 U.S. 397, 407 (1932) ("In contemplation of law the claim for damages arose at the time the extra charge was paid."). However, the parties disagree as to whether that same injury standard should apply to EPPs' state law antitrust claims. EPPs contend that the federal antitrust standard, under which injury occurs the moment of overcharge, applies to the state law claims. EPPs' Class Cert. Mem. 24. Defendants disagree, asserting that the Court has an obligation to determine whether each

state would apply an actual economic harm standard, and that under the correct state law standards for injury, EPPs are required to prove that they suffered actual economic harm from the overcharge, and did not pass on that overcharge to others. Defs.' Opp'n Class Cert. 66–68.

In order to assess the antitrust injury standard for state law claims, it is important to first review the jurisprudential backdrop against which EPPs bring their antitrust claims.

In *Hanover Shoe*, the Supreme Court held that antitrust plaintiffs could recover the full amount of their overcharge damages, and antitrust defendants could not raise the defense that plaintiffs were unharmed because plaintiffs passed to others any overcharges that they had paid. *Hanover Shoe, Inc. v. United Shoe Mach. Corp*., 392 U.S. 481, 491–93 (1968). The Supreme Court chose to abolish this pass-on defense because "establishing the applicability of the passing-on defense would require a convincing showing of each of these virtually unascertainable figures [and] the task would normally prove insurmountable . . . Treble-damage actions would often require additional long and complicated proceedings involving massive evidence and complicated theories." *Id*. at 493.

In *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), the Supreme Court "made the symmetrical decision, consistent with *Hanover* [*Shoe*], to disallow an offensive use of the [pass-on] theory." *In re Lower Lake Erie Iron Ore Antitrust Litig*., 998 F.2d 1144, 1164 n.10 (3d Cir. 1993). "[J]ust as *Hanover Shoe* wanted to avoid burdening antitrust plaintiffs from nearly-impossible evidentiary challenges, *Illinois Brick* reflected the Supreme Court's 'perception of the uncertainties and difficulties in analyzing price and out-put decisions in the real economic world . . . and of the costs to the judicial system and the efficient enforcement of the antitrust laws of attempting to reconstruct those decisions in the courtroom.'" *In re Processed Egg Prod. Antitrust Litig*., 881 F.3d 262, 270 (3d Cir. 2018). Under *Illinois Brick*, federal antitrust claims

by indirect purchasers were barred. However, *Illinois Brick* did not preempt indirect purchasers from bringing antitrust actions under state antitrust laws. *California v. ARC Am. Corp*., 490 U.S. 93, 105–06 (1989). In the present action, EPPs bring their antitrust claims under laws by "*Illinois Brick* repealer states" that have passed statutes enabling indirect purchasers to bring antitrust claims under state law. EPPs' Reply Class Cert. 35; *see generally In re Flonase Antitrust Litig*., 284 F.R.D. 207, 214 n.9 (E.D. Pa. 2012) (describing "*Illinois Brick* repealers").

Defendants argue that "[t]he federal overcharge measure of injury that EPPs rely upon is a legal construct that, for reasons grounded in federal antitrust policy, permit direct purchasers to recover the entire overcharge even if they 'passed on' the overcharge to others and suffered no actual economic harm." Defs.' Opp'n Class Cert. 67 (citing *Hanover Shoe, Inc. v. United Shoe Mach. Corp*., 392 U.S. 481, 494 (1968)). They state that "EPPs just assume, without any analysis of specific state laws, that the federal measure of injury for direct purchaser claims applies to their indirect purchaser claims [and that EPPs'] assumption makes no sense, as a matter of law or policy." Defs.' Opp'n Class Cert. 67. Defendants argue to the contrary that the Court must assess each state statute, and absent "a definitive ruling by a state's highest court, [this Court] must predict how that court would rule if faced with the issue." *Id*. at 68 (citing *Covington v. Cont'l Gen. Tire, Inc.*, 381 F.3d 216, 218 (3d Cir. 2004)).

EPPs respond that "[t]he class states repealed *Illinois Brick Co. v. Illinois*'s prohibition against indirect purchaser antitrust actions, but they did not repeal the century of federal antitrust law preceding *Illinois Brick*[,] . . . includ[ing] the well established principle that 'antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset.'" EPPs' Reply Class Cert. 35 n. 55.

The Court agrees with EPPs that *Illinois Brick* repealer states have applied the federal overcharge injury standard. Defendants' argument conflates the policy that the Supreme Court articulated with respect to treatment of the pass-on defense in *Hanover Shoe* and the offensive use of the pass-on theory in *Illinois Brick* with the longstanding antitrust principle that injury occurs at the moment of overcharge. *See, e.g.*, *Adams v. Mills*, 286 U.S. 397, 407 (1932); *S. Pac. Co. v. Darnell-Taenzer Lumber Co.*, 245 U.S. 531, 534 (1918). The "federal" overcharge standard of antitrust injury is distinct from the policy judgments implicated by *Hanover Shoe* and *Illinois Brick* and the subsequent passage of the state statutes repealing *Illinois Brick*.

EPPs contend that defendants' argument "is based on the faulty legal premise that injury and damages are synonymous." EPPs' Class Cert. Mot. 34. The Court agrees with EPPs on that issue.

Proof of antitrust injury or impact is analytically distinct from proof of antitrust damages. *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 194 (3d Cir. 2020) ("We have consistently distinguished injury from damages."); *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 188 (3d Cir. 2001) ("Proof of injury (whether or not an injury occurred at all) must be distinguished from calculation of damages (which determines the actual value of the injury)."). "[T]he purpose of the antitrust injury requirement is to prove that the theory of unlawful conduct, i.e. the theory of liability, was in fact responsible for causing harm to plaintiffs." *In re Niaspan Antitrust Litig.*, No. 13-2460, 2019 WL 3816829, at *14 (E.D. Pa. Aug. 14, 2019). The availability of a pass-on defense has no bearing on proof that a plaintiff sustained "some harm traceable to the defendant's conduct." *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305 (3d Cir. 2016). To the extent that pass-on defense is available, it relates to the calculation of damages, not the standard of antitrust injury. *See In re Cardizem CD*

Antitrust Litig., 200 F.R.D. 297, 317 (E.D. Mich. 2001) ("Defendants' by-pass and offsetting benefits arguments relate to the quantum of damages; not the fact of injury."); *see also In re Vitamins Antitrust Litig.*, 259 F. Supp. 2d 1, 8–9 (D.D.C. 2003) (permitting a pass-on defense as a challenge to "plaintiff's damage estimates").

The Court concludes that EPP class members sustained antitrust injury at the moment they were overcharged. This decision is consistent with the approach adopted by other courts considering state law claims in similar antitrust actions by indirect purchasers. *See In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015) ("[A]ntitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset."); *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *14 (D.N.J. Oct. 30, 2018) (holding that subsequently recovered damages are "irrelevant to the question of impact"); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-02503, 2017 WL 4621777, at *15 (D. Mass. Oct. 16, 2017) ("[E]ven if putative class members were reimbursed for overcharges through insurance plans or coupons, they still experienced antitrust injury in the form of an overcharge, although the amount of damages may require adjustment."); *In re Lidoderm Antitrust Litig.*, No. 14-02521, 2017 WL 679367, at *21 (N.D. Cal. Feb. 21, 2017) ("[T]he Court concludes that a person suffers a cognizable injury and is impacted by a price-fixing conspiracy at the moment he pays an antitrust overcharge, even if the anticompetitive conduct at issue also results in offsetting benefits.").

Thus, for purposes of the predominance inquiry, EPPs may satisfy their burden of showing common evidence of antitrust injury by establishing that each class member paid an overcharge, regardless of whether that overcharge was subsequently passed on to others.

3. *EPPs' Common Proof of Injury*

EPPs present an expert report from Dr. Meredith Rosenthal to support their claim that they have common proof of antitrust injury arising from the delay in generic entry. Dr. Rosenthal relies on extensive evidence, including a Federal Trade Commission ("FTC") study finding that "generic price discounts with respect to the pre-launch branded price reach 17% after 6 months," at which point generics hold 83.7% of the market share. Expert Rep. Meredith Rosenthal, Ph.D. ("Rosenthal Rep.") ¶ 37. According to Dr. Rosenthal, the actual launch of generic Niaspan resulted in a 33% price discount after 6 months, at which point generic Niaspan garnered 79% of the market share. *Id*. Dr. Rosenthal also notes that defendant AbbVie's internal analyses anticipated results similar to the FTC study, namely, "a generic penetration rate starting at 30% in the first month and reaching nearly 90% assuming two generic products." *Id*.

Based on this research, Dr. Rosenthal employs a "yardstick model," which compares the actual prices and quantities in the market of interest to the prices and quantities that occur in a similar market untainted by the delay of generic entry and foreclosure of lower prices. *Id*. ¶ 27. She bases her yardstick calculations on AbbVie's internal analysis and the FTC study results, and assumes an average rate of generic substitution of 87.8% from Kos' own internal forecasting. *Id*. ¶ 38.

Dr. Rosenthal concludes that "the likelihood that a consumer who paid for Niaspan during the Class Period would not have paid for at least one prescription of the generic in the but-for world is small – 100 minus 87.8 or 12.2%. Moreover, because Niaspan is a maintenance drug most potential Class members will have many prescriptions and thus repeated opportunities to be offered and try the generic." *Id*. ¶ 39. With respect to TTPs, Dr. Rosenthal opines that, assuming a TPP pays for at least ten independent Niaspan claims, "the likelihood that a payer

with only 10 claims for Niaspan in the actual world had no generic claims in the but-for world is approximately 0.000000001 or 1 in 1 billion." *Id.* ¶ 38.

According to EPPs, "the analysis conducted by Dr. Rosenthal demonstrates that virtually all class members were injured on at least one transaction by the unlawful delay in generic Niaspan competition."[8] EPPs' Class Cert. Mem. 33.

4. *Defendants' Challenges to EPPs' Common Proof of Injury*

Defendants argue that contrary to EPPs' assertions, Dr. Rosenthal's report does not provide common evidence of antitrust injury. Defs.' Opp'n Class Cert. 51–55. Defendants highlight Dr. Rosenthal's deposition testimony in which she conceded she does not opine that all class members were injured, and that her aggregate damages analysis does not show which individual class members were uninjured. *Id.* at 52. As defendants' expert, Professor James Hughes, opines, "if [Dr. Rosenthal's] damages model were reliable, which it is not, at best she could establish the average 'overcharge' per prescription paid by the class. But this average overcharge simply does not speak to whether any or all individual class members were injured." Expert Rep. Prof. James W. Hughes, Ph.D. ("Hughes Rep.") ¶ 119. Defendants contend that Dr. Rosenthal's reliance on averages impermissibly hides uninjured class members. In support, they rely on Professor Hughes' analysis of transactional data produced by ten EPP named plaintiffs. Defs.' Opp'n Class Cert. 54. After reviewing the data, Professor Hughes concluded that "there is wide heterogeneity across Named Plaintiffs in total prescription costs for Niaspan, ranging from $0 to over $1,000 per prescription," and that "[p]ayments made by consumers of Niaspan and

[8] EPPs argue that they are entitled to a presumption of causation that the class sustained classwide injury. EPPs' Class Cert. Mem. 24–25. They claim that "an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct 'is deemed wrongful because it is believed significantly to increase the risk of a particular injury' and that injury occurred." *Id.* at 24 (citing *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 101 (2d Cir. 2017)). The Court agrees with defendants that *Actos* does not diminish EPPs' burden of proving classwide antitrust injury. *See* Defs.' Opp'n Class Cert. 56.

generic niacin also vary considerably across consumers and also deviate substantially from Professor Rosenthal's calculated average, ranging from $0 to over $250." Hughes Rep. ¶ 122. Defendants argue that Dr. Rosenthal's assertion that Niaspan users will likely make at least one generic purchase "ignores studies that showed more than 40 percent of patients stopped taking Niaspan after the first three months, and only 16 percent continued to take Niaspan after one year." Defs.' Opp'n Class Cert. 26.

Defendants further argue that "there are numerous examples of circumstances in which potential class members would not have suffered any injury from the alleged delay in generic entry, and for which there is no way to identify those class members without individualized inquiries." Defs.' Opp'n Class Cert. 57. These groups include (1) consumers and TPPs who still would have paid for brand Niaspan after generic Niaspan was introduced (brand loyalists), (2) uninjured consumers due to copay assistance, (3) consumers fully reimbursed by health reimbursement accounts ("HRAs"), (4) flat co-payors, (5) consumers who filled all Niaspan prescriptions in the Medicare Part D coverage gap, (6) TPPs that would have paid the same or more for generic Niaspan than brand Niaspan, and (7) rebates.

The Court first considers defendants' challenges to EPPs' use of averages to prove classwide injury, and then addresses the defendants' claims regarding specific subgroups of uninjured class members.

a. EPPs' Use of Averages To Prove Classwide Injury

The Court must determine whether Dr. Rosenthal's use of averages in her yardstick model masks uninjured class members or can be used to prove common classwide injury. The answer: Dr. Rosenthal does not provide common evidence of classwide injury; proof of injury

would involve individualized inquiries that defeats predominance. Dr. Rosenthal's use of averages to determine classwide injury thus masks uninjured class members.

"The use of averages in a common impact analysis is controversial, and courts have come down on both sides of the issue at the class certification stage . . . Essentially, the case law seems to compel the court to view averages as at least somewhat suspect, but not as fatally flawed so long as (1) the differentiation among the data being averaged is not so great as to make the use of averages misleading; and (2) there are other indicia that the averages are not concealing the true story of the data." *In re Blood Reagents Antitrust Litig*., No. 09-2081, 2015 WL 6123211, at *18 (E.D. Pa. Oct. 19, 2015) (DuBois, J.) (citing *In re Processed Egg Prod. Antitrust Litig*., 81 F. Supp. 3d 412, 428 (E.D. Pa. 2015)). "Averages are also more of a problem when plaintiffs seek to certify a class of indirect purchasers." *In re Lamictal Indirect Purchaser & Antitrust Consumer Litig*., No. 12-00995, 2018 WL 6567709, at *7 (D.N.J. Dec. 12, 2018), *rev'd on other grounds* 957 F.3d 184 (3d Cir. 2020). On this issue, the Third Circuit recently cautioned that courts should not assume, "absent a rigorous analysis, that averages are acceptable." *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d at 194.

EPPs contend that Dr. Rosenthal's proposed damages model uses common evidence to show class-wide injury, and "is constructed by reference to the well-researched and accepted understanding in the scholarly literature of the impact of generic competition on drug prices, real world data reflecting the prices and volume of brand and generic Niaspan, in addition to the prices and quantities sold for 'yardstick' products." EPPs' Reply Class Cert. 44. They argue that the variation is not so wide as to mask uninjured members. *Id*. According to EPPs, this case is similar to *Flonase*, another pay-for-delay case, in which plaintiffs submitted expert evidence of common injury based on a yardstick analysis. *Id*. at 44 n.66 (citing *In re Flonase Antitrust*

Litig., 284 F.R.D. 207, 222 (E.D. Pa. 2012). In that case, the court was "satisfied that the data variation in this case [was] not so extreme as to mask the absence of injury for a significant number of class members." *Id*. at 229.

Defendants argue that *Flonase* is inapposite. May 14 Tr. 191:7–15. In *Flonase*, plaintiffs' expert conducted a sensitivity analysis, which assured the court that the averages did not mask significant variation. *Id.*; *In re Flonase Antitrust Litig*., 284 F.R.D. at 228–229. In addition, defendants correctly note that the *Flonase* court was only satisfied that the averages did not mask significant variation after excluding several groups of potentially uninjured plaintiffs, including (1) uninsured consumers who purchased brand Flonase after generic entry; (2) all consumers who purchased brand Flonase prior to generic entry and did not purchase brand or generic Flonase after generic entry; and (3) TPPs that only purchased and/or reimbursed brand Flonase but never generic Flonase during the Class Period. *In re Flonase Antitrust Litig*., 284 F.R.D. at 230–232. Significantly, *Flonase* was decided prior to the Third Circuit adoption of the ascertainability requirement, so the court was able to exclude potentially uninjured purchasers without considering whether purchasers falling within those exclusions were reasonably ascertainable. *Id*.; May 14 Tr. 192:4–6. Thus, *Flonase* is distinguishable from this case.

EPPs correctly state that evidence of delay in generic entry that results in overcharges can in some cases suffice to show classwide evidence of injury. EPPs' Reply Class Cert. 44, 52–53. However, the substantial variation in prices reported by Dr. Hughes among the sliver of data produced by named plaintiffs—$0 to over $1,000 per prescription for TPPs, and $0 to over $250 for consumers—raises cause for concern in this case. *See* Hughes Rep. ¶ 122. EPPs do not contest Dr. Hughes' analysis, but instead observe that "most transaction prices clustered around

[Dr. Rosenthal's] average prices, and that any variations follow a discernable trend alongside the average prices." EPPs' Reply Class Cert. 52 n.75.

The Court concludes that the averages in Dr. Rosenthal's yardstick model do not suffice to prove classwide injury for EPPs in this case. Critically, Dr. Rosenthal conceded that her yardstick model does not purport to show that all class members were injured. Defs.' Opp'n Class Cert. 52 (citing Rosenthal Dep. 62:21–63:5). The Court finds this case analogous to *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, in which plaintiffs also relied on the expert testimony of Dr. Rosenthal. In that case, Judge Stengel conducted "[a] 'rigorous analysis' of Dr. Rosenthal's reports and testimony" and concluded "it does not show that *all* class members paid supra-competitive prices for generic or branded sustained release bupropion, or that this determination can be made with common proof." No. 04-5898, 2010 WL 3855552, at *26 (E.D. Pa. Sept. 30, 2010). In *GlaxoSmithKline*, Dr. Rosenthal admitted that certain class members may be uninjured, and that her analysis would be unable to identify them, leading the court there to conclude that the proffered yardstick model masked groups of uninjured class members. *Id*. at *30. As Judge Stengel noted in rejecting the proposed yardstick methodology, "the issue is not whether [the] techniques are generally accepted; it is whether they are appropriate when applied to the facts and data *in this case*." *Id*. (internal quotations omitted and emphasis in original). In this case, the Court concludes that the use of averages hides several groups of uninjured class members who cannot be easily identified.

b. Means of Removing Uninjured Class Members

Defendants argue that EPPs further fail the predominance requirement because there are large categories of uninjured class members that EPPs have not identified and cannot identify without individualized inquiry. Defs.' Opp'n Class Cert. 57. Specifically, defendants point to

brand loyalists, consumers who are uninjured due to co-payment assistance, health reimbursement accounts ("HRAs"), flat co-payors, consumers who filled all Niaspan prescriptions during a Medicare Part D coverage gap, TPPs paying the same or more for generic Niaspan than for brand Niaspan, and TPPs that received brand rebates. In response, EPPs assert that "virtually all class members were injured on at least one transaction by the unlawful delay in generic Niaspan competition." EPPs' Reply Class Cert. 33.

To the extent that a proposed class contains uninjured class members, plaintiffs must provide a reasonable and workable method for differentiating between uninjured class members and injured class members so that uninjured class members do not recover damages. *In re Asacol Antitrust Litig.*, 907 F.3d 42, 58 (1st Cir. 2018). Such a method must be protective of a defendant's constitutional rights and not cause individual inquiries to overwhelm common issues. *Id.*; *see also Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *21 (E.D. Pa. June 10, 2015) ("Without a means of identifying these uninjured persons using common evidence, every class member would need to be reviewed on an individualized basis to see if they were impacted by Defendants' alleged anticompetitive actions."). Moreover, for purposes of the predominance analysis, the number of potentially uninjured class members is a relevant consideration. While it is perfectly reasonable for the Court to address challenges to a small number of uninjured class members, "it would be far more difficult for a court to 'weed out' over 2,000 uninjured class members—or some subset of that number—from a class of over 16,000." *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 292 F. Supp. 3d 14, 137–38 (D.D.C. 2017); *see also In re Intuniv Antitrust Litig.*, No. 16-12396, 2019 WL 3947262, at *8 (D. Mass. Aug. 21, 2019). In this case, there are an estimated 600,000 class members, any of whom may

be uninjured, and according to defendants, there are thousands who in fact suffered no injury. *See In re Asacol Antitrust Litig.*, 907 F.3d at 53–54.

The Court next addresses defendants' arguments on the issue of uninjured class members.

i. Brand Loyalists

The first and most significant group of uninjured, unidentified class members are consumer brand loyalists, who were unharmed by delayed generic entry because they would have continued buying brand Niaspan regardless of any price difference between brand and generic Niaspan. Dr. Rosenthal calculated that 12.2% of purchases after generic entry would remain brand purchases. Rosenthal Rep. ¶ 39.

Defendants contend that "there is simply no mechanism to determine which prescriptions [the 12.2% of continued brand purchases after generic entry] would have been, and who would have paid for them, without class-member-specific and even transaction-specific inquiries." Defs.' Opp'n 57.

EPPs first respond that "[d]ue to state automatic substitution laws, all or virtually all Niaspan consumers would try generic Niaspan at least once, even if they ultimately chose to return to the brand at a higher price." EPPs' Reply Class Cert. 49 (citing *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27–30 (1st Cir. 2015). EPPs have provided no evidence regarding the specific terms of such state laws. This omission is significant because, while all states have such laws, not all states make substitution mandatory.

EPPs also argue that they have accounted for brand loyalists by excluding consumers who purchased only brand Niaspan after generic entry on September 20, 2013, and argue that such purchasers can be identified. EPPs' Reply Class Cert. 23. They assure the Court that they can create a database by which they can systematically apply the brand loyalist exclusion. *Id.*

For the reasons discussed when analyzing class ascertainability, the Court doubts whether EPPs can feasibly produce such a database and systematically apply the brand loyalist exclusion.

Even assuming *arguendo* that EPPs could identify the brand loyalists that purchased only brand Niaspan after generic entry, EPPs have no means of identifying brand loyalists who purchased brand Niaspan prior to generic entry but made no purchases of brand or generic Niaspan after generic entry. EPPs respond with three arguments. The Court rejects EPPs' arguments.

First, EPPs argue that "such consumers cannot properly be considered brand loyalists because generic Niaspan was not yet available on the market, they lacked an opportunity to demonstrate any preference for or 'loyalty' to branded or generic Niaspan." EPPs' Reply Class Cert. 25. This response fundamentally misconceives the objective of the inquiry, which is to assess whether a purchaser *would have* purchased cheaper generic Niaspan had that option been available. This Court is aware of no court that has adopted this unfounded argument, and it declines to do so in this case.

Second, EPPs argue that the presence of unidentified, uninjured brand loyalists in the class does not prejudice defendants. EPPs' Reply Class Cert. 25. Specifically, they assert that Dr. Rosenthal factored in the presence of brand loyalists and calculated damages only for those class members who would have switched to generic Niaspan or who purchased the generic at inflated prices so "defendants have no interest tied to the exclusion of purported brand loyalist class members." *Id*. at 26.

EPPs' argument that defendants have no interest in the exclusion of uninjured class members has been rejected by the Third Circuit. *See Carrera v. Bayer Corp*., 727 F.3d 300, 310 (3d Cir. 2013) ("[Defendant] has an interest in ensuring it pays only legitimate claims. If

fraudulent or inaccurate claims materially reduce true class members' relief, these class members could argue the named plaintiff did not adequately represent them [and they are not bound by the judgment."); *see also In re Asacol Antitrust Litig.*, 907 F.3d 42, 56 (1st Cir. 2018) ("Once one accepts plaintiffs' 'no harm, no foul' position there would be no logical reason to prevent a named plaintiff from bringing suit on behalf of a large class of people, forty-nine percent or even ninety-nine percent of whom were not injured, so long as aggregate damages on behalf of 'the class' were reduced proportionately. Such a result would fly in the face of the core principle that class actions are the aggregation of individual claims, and do not create a class entity or re-apportion substantive claims.").

Finally, EPPs argue "it would be inappropriate to exclude from the classes individuals who purchased Niaspan solely prior to generic entry because it would permit Defendants to benefit from their own illegal conduct." EPPs' Reply Class Cert. 26. However, this argument is unavailing, as under Rule 23, it is EPPs who bear the burden of proof. "The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only," *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 248 (3d Cir. 2016), and for EPPs to take advantage of the class action device, EPPs must limit their class to an operational definition. *See, e.g.*, *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 232 (E.D. Pa. 2012) (excluding class members who did not make any purchases of brand or generic Flonase after generic entry to avoid potential brand loyalists).

The Court concludes that there are a substantial number of brand loyalists in the class, and EPPs have the burden of showing that excluding them can be accomplished without extensive individualized inquiry. EPPs have provided no "reasonable and workable plan for how [the opportunity to press at trial genuine challenges to allegations of injury-in-fact] will be

provided in a manner that is protective of the defendant's constitutional rights and does not cause individual inquiries to overwhelm common issues." *Thalomid*, 2018 WL 6573118, at *12. Accordingly, the Court concludes that identification of consumer brand loyalists would require extensive individualized inquiries and defeat predominance. *See Vista Healthplan, Inc. v. Cephalon, Inc*., No. 06-1833, 2015 WL 4737288, at *19 (E.D. Pa. Aug. 4, 2015);[9] *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, No. 04-5898, 2010 WL 3855552, at *25 (E.D. Pa. Sept. 30, 2010).

Thus far, the brand loyalist discussion has focused on consumer purchasers. With respect to TPP brand loyalists, Dr. Rosenthal opined that the likelihood that a payor with only 10 independent claims for Niaspan had no generic claims is approximately 1 in 1 billion. Rosenthal Rep. ¶ 38. As a result, EPPs state there is no brand loyalist concern for TPPs with many independent claims. In response, defendants point out that there are over 20,000 self-insured health plans and over 4,000 mixed health plans, many of which are very small and would have made only a few purchases, thereby rendering it more likely that at least some of the TPPs are uninjured. May 14 Tr. 188:7–15. For example, defendants point to the fact that from 2014 to 2016, named TPP plaintiff AF of L paid for only 31 months of Niaspan for only three beneficiaries. *Id*. at 188:16–23.

Even if a TPP reimbursed only three beneficiaries, it would remain unlikely that all the TPP's reimbursements were for brand loyalists. On the current state of the record, the Court concludes that the number of any TPP brand loyalists is *de minimis*.

[9] EPPs provided notice to the Court that Judge Goldberg recently certified a settlement class in *Vista Healthplan, Inc. v. Cephalon, Inc*., No. 2:06-cv-01833, slip op. at 1 (E.D. Pa. Apr. 21, 2020). However, Judge Goldberg made clear that the prospect of settlement impacted his analysis of both ascertainability and predominance. *Id.* at 24-25, 28. Indeed, many of the concerns at issue in certifying a litigation class are alleviated after settlement. *See In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. at 151 n.8 ("In certifying a litigation class, the Court must be mindful of a defendant's due process rights. Such a concern is not present when administering a settlement class.").

ii. Uninjured Consumers Due to Co-payment Assistance

Defendants argue that EPPs have made no attempt to determine whether there are uninjured class members due to coupon use—that involvement in a coupon co-payment assistance program resulted in some purchasers paying less for branded Niaspan than they would have paid for generic Niaspan had it been available. Defs.' Opp'n Class Cert. 61–62. Dr. Hughes estimates that 3–4% of brand Niaspan purchases were made with co-payment assistance coupons that included $0 co-payment coupons, $50 off co-payment coupons, and $25 maximum co-payment coupons, *id*. at 61, whereas Dr. Rosenthal estimates that 2.4% of prescription purchases involved coupon use. *Id*. at 62 n.27.

Defendants claim that they "are entitled to defend against individual claims by testing whether class members used copay assistance and did not pay an overcharge, necessitating individualized inquiries." *Id*. at 62. Defendants further contend that given the drug's low persistency rate, there were likely many consumers who used coupons for all of their purchases. *Id*. at 61–62.

EPPs respond that defendants concede that coupons apply to less than 4% of transactions and would affect "only a handful of customers." EPPs' Reply Class Cert. 22. However, even if only a small percentage of consumers were uninjured due to coupon use, the sheer class size creates significant difficulties for manageably addressing defendants' challenges. *In re Rail Freight Fuel Surcharge Antitrust Litig*., 292 F. Supp. 3d 14, 137–38 (D.D.C. 2017).

EPPs also state that "even if there were a small substantiated subset of uninjured 'all-coupon' consumers—and there is not—these consumers can be identified and programmatically

excluded from the subclasses" because "pharmacies track coupon usage on a transactional basis, including the coupon value, prescription fill date, and identity of the consumer." EPPs' Reply Class Cert. 22. Assuming *arguendo* that adequate records tracking coupon use on all Niaspan purchases could be produced prior to trial, defendants have the right to present evidence to the jury that a subset of class members did not suffer antitrust injury because of their coupon use. *See In re Asacol Antitrust Litig.*, 907 F.3d 42, 58 (1st Cir. 2018) ("[C]ertainly where injury-in-fact is a required element of a claim, as it is in an antitrust action, a class cannot be certified based on an expectation that the defendant will have no opportunity to press at trial genuine challenges to allegations of injury-in-fact." (internal citations omitted)). EPPs have offered no means of manageably addressing such challenges in a manner that would not defeat predominance. EPPs' failure to identify a non-individualized means of addressing uninjured consumers due to coupon use weighs against class certification.

iii. Health Reimbursement Accounts

Defendants argue that consumers who were subsequently fully reimbursed by HRAs for their Niaspan and generic Niaspan payments had no damages and are therefore uninjured. Defs.' Opp'n Class Cert. 62. EPPs respond that "[t]hird-party reimbursements under HRAs—to the unsubstantiated extent they occur at all for Niaspan—are irrelevant to the issue of whether consumers were injured" because the purchasers were injured as soon as they paid the overcharge. EPPs' Reply Class Cert. 23. The Court agrees with EPPs that injury occurs at the time of an unlawful overcharge, and any subsequent reimbursement is irrelevant.

Defendants raise the possibility that some purchasers may be uninjured because they paid for brand Niaspan with debit cards issued and paid for by their employer. Defs.' Opp'n Class Cert. 10 n.2; May 14 Tr. 195:20–196:1. Defendants do not even attempt to estimate the

prevalence of such uninjured class members. On this issue the Court concludes that, to the extent that the class contains such uninjured members, that number is *de minimis* and does not preclude certification.

iv. Flat Co-Payors

Defendants further argue that 4–9% of consumers had flat co-pays during the class period and would have paid the same for generic as brand Niaspan and therefore are uninjured. Defs.' Opp'n Class Cert. 58–59, 64.

EPPs respond that they "have established that records exist to identify plans by copayment structure, which can then be sorted by a data analytics firm to exclude transactions associated with a flat copay." EPPs' Reply Class Cert. 49–50.

To the extent that the identification of flat co-payors, which are excluded from the class definition, cannot be differentiated from other class members without extensive individualized inquiry, flat co-payors pose a predominance problem in addition to an ascertainability problem. As the Court discussed with respect to ascertainability, the Court is not convinced that EPPs have a method of differentiating flat co-payors from other class members through a means that avoids extensive individualized inquiries. Absent a systematic means of excluding flat co-payors, defendants would be entitled to present individualized evidence to a jury that certain Niaspan purchasers are uninjured due to a flat co-pay structure and are therefore excluded from the class definition. *See Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *19 (E.D. Pa. June 10, 2015) ("When the identification and exclusion of these consumers cannot be managed without considering the highly individualized purchasing history of individuals and their specific insurance plans, simply stating that they are excluded from the class definition is not sufficient to show that common issues will predominate.").

v. Consumers Who Filled all Niaspan Prescriptions After Reaching a Medicare Part D Coverage Gap

Defendants assert that consumers who filled Niaspan prescriptions in a Medicare Part D coverage gap may not have incurred an overcharge because their coinsurance rates were lower for branded than generic drugs. Defs.' Opp'n Class Cert. 59.

EPPs contend that defendants' hypothetical is highly speculative, so "it is no surprise that neither Defendants nor Dr. Hughes identify a single consumer who meets these criteria nor attempt to estimate their prevalence." EPPs' Reply Class Cert. 50. They note that in order to reach the coverage gap,

> a Part D consumer must first reach their out-of-pocket deductible and then pay a copayment or coinsurance on their prescriptions until reaching their initial coverage limit. Only after surpassing these two coverage thresholds does a Part D consumer enter the coverage gap and allegedly pay less for brand Niaspan-and even then, only through the end of that policy period. A consumer would need to fill all of their Niaspan prescriptions only after entering the Part D coverage gap in every period during which they were prescribed Niaspan to be uninjured.

Id. The Court agrees with EPPs that defendants' argument rests on an unfounded hypothetical and "defendants' speculation cannot defeat certification." *In re Thalomid & Revlimid Antitrust Litig*., No. 14-6997, 2018 WL 6573118, at *23 (D.N.J. Oct. 30, 2018).

vi. TPPs Paying the Same or More for Generic Niaspan than Brand Niaspan

Defendants assert that there are multiple scenarios in which TPPs would not have paid an overcharge because they would have paid the same or more for generic Niaspan than for brand Niaspan. Defs.' Opp'n Class Cert. 59. Dr. Hughes hypothesizes that "if the retail price of the brand drug is $100 and $83 for the generic, and the consumer's copayment is $30 for a preferred brand drug and the generic copayment is $10 (as was the case for certain City of Providence plans), then the TPP would pay $70 for the brand but $73 for the generic." *Id.* Defendants also

highlight that Dr. Hughes found that, for two named TPP plaintiffs, "the effective cost to TPPs for Niaspan just before actual generic entry [was] often lower than for generic niacin after actual generic entry." *Id*. at 54.

EPPs argue that the TPPs would have to have an unfavorable co-pay on every single payment, and note that in Hughes' two examples, for one insurer, twelve of the fifteen claims for generic Niaspan were less than the brand, and for the other, generic Niaspan claims were less in five out of eight transactions. EPPs' Reply Class Cert. 50. EPPs also persuasively note that Hughes not only failed "to identify a single Plaintiff that would have paid more on every generic Niaspan transaction for even one insured member in a competitive world, [he also failed to] even estimate the likelihood of that situation actually occurring for any TPP across all its members." *Id*.

The Court is convinced by EPPs' argument; given Dr. Hughes' failure to even estimate the prevalence of uninjured TPPs, the Court concludes that the number of TPPs in this hypothetical category is *de minimis*.

vii. Rebates

Defendants also argue that TPPs may have received brand rebates, which would further lower the costs of brand Niaspan and could result in generic Niaspan being more expensive. Defs.' Opp'n Class Cert. 60–61. Plaintiffs respond that there is no legal basis to argue that rebates negate antitrust injury, and instead would act as a "damages set-off." EPPs' Reply Class Cert. 48.

The Court agrees with EPPs. *See In re Thalomid & Revlimid Antitrust Litig*., No. 14-6997, 2018 WL 6573118, at *14 ("[A]s Plaintiffs correctly argue, any amounts that such Plan Sponsors received in coverage or in the form of rebates is irrelevant to the question of impact.").

Defendants argue that some rebates are different in that they do not operate as reimbursements but rather are credited towards the cost of prescriptions at the time of the invoicing. Defs.' Opp'n Class Cert. 61 n.26. This latter type of rebate could negate antitrust impact, or injury. *See In re Nexium Antitrust Litig.*, 777 F.3d 9, 28 (1st Cir. 2015). However, defendants do not even attempt to quantify the prevalence of such rebates, and on the present state of the record, the Court concludes that such rebates are *de minimis*.

viii. Conclusion: Uninjured Class Members

In sum, the Court is concerned that the class contains, at minimum, substantial numbers of uninjured consumer brand loyalists, coupon users, and flat co-payers.[10] The Court is not satisfied that EPPs have a non-individualized means of identifying these uninjured class members in a way that protects defendants' constitutional rights. *See, e.g.*, *In re Intuniv Antitrust Litig.*, No. 16-12396, 2019 WL 3947262, at *8 (D. Mass. Aug. 21, 2019) (holding predominance not satisfied because plaintiffs "have not put forth a reasonable and workable plan to weed out uninjured class members"); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 53–54 (1st Cir. 2018) ("The need to identify those [uninjured] individuals will predominate and render an adjudication unmanageable absent evidence . . . [of] some . . . mechanism that can manageably remove uninjured persons from the class in a manner that protects the parties' rights."). The Court concludes that EPPs lack common evidence of antitrust injury, and cannot satisfy the Rule 23(b)(3) predominance requirement.

[10] EPPs' contention that "[d]efendants have not rebutted Plaintiffs' common evidence of injury with any substantiated example of a specific uninjured class member in the record," EPPs' Reply Class Cert. 34, is unpersuasive in light of the expert testimony discussed above and the extremely limited data production in the case.

5. *Defendants' Challenge to EPPs' Aggregate Damages Model*

Defendants also challenge EPPs' classwide aggregate damages model. At class certification, "a model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to that theory." *In re Niaspan Antitrust Litig.*, No. 13-2460, 2019 WL 3816829, at *14 (E.D. Pa. Aug. 14, 2019) (citing *Comcast v. Behrend*, 569 U.S. 27, 35 (2013).

Defendants argue that "there is a mismatch between the EPPs' aggregate damages model and their exclusion of PBMs from . . . class membership," because "PBMs sometimes end up paying for part of the cost of prescriptions charged by pharmacies." Defs.' Opp'n Class Cert. 64–65. In support of their position, defendants assert that "the record contains documentary evidence of Caremark, a PBM, making a $333,906 payment to the City of Providence in order to perform a price guarantee. On this issue, Mr. Winkelman acknowledged that, in his experience auditing PBM contracts, around half of the time the PBM ended up having to make a payment to perform on price guarantees." *Id*. at 65.

EPPs respond that "[t]here is no merit to Defendants' argument that the role of PBMs—intermediary service providers who do not insure or pay for beneficiary purchases— somehow fatally wounds EPPs' damages model under *Comcast*." EPPs' Reply Class Cert. 44–45. They contend that "[d]efendants have completely failed to substantiate their argument that PBMs actually suffer losses on Niaspan purchases through the mechanics of their price negotiations on behalf of TPPs. Indeed, the PBMs themselves disavow this theory." *Id*. at 45. As Robert Lahman of OptumRx stated,

> As a PBM, OptumRx does not consider itself to be paying for its Clients' prescription drug purchases. While OptumRx may retain, in certain cases, compensation through spread pricing, rebates, or administrative fees, that compensation is payment for services that OptumRx provides and not payment for

> prescription drugs that are dispensed to health plan members and which are the financial responsibility of the health plan.

Lahman Decl. ¶ 11. EPPs further note that defendants' Caremark example does not show that any of the repayment in question was attributable to Niaspan purchases. EPPs' Reply Class Cert. 45.

Courts considering this argument in similar cases have recognized that a PBM's payment of part or all of the overcharge for the cost of prescriptions charged by pharmacies, "would create issues either with ascertainability or, if PBMs are excluded, with the classwide damages model." *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *23 (D.N.J. Oct. 30, 2018); *see also In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 149 (E.D. Pa. 2015) (noting if PBMs were excluded from the class definition, "[plaintiffs'] current damages model would potentially include damages suffered by non-class members, and may therefore overstate the amount of damages suffered by the [class]."). However, courts have rejected this challenge in cases in which the defendants did not provide evidence that PBMs may have paid pharmacies more for a drug than the payment they received from a TPP, and therefore dismissed the challenge as a "general, theoretical risk." *In re Thalomid & Revlimid Antitrust Litig.*, 2018 WL 6573118, at *23; *In re Lidoderm Antitrust Litig.*, No. 14-02521, 2017 WL 679367, at *25 (N.D. Cal. Feb. 21, 2017).

In this case, the Court agrees with EPPs that defendants have not provided evidence that any PBM payments based on price guarantees resulted in a loss on Niaspan purchases, and further credits the statement by OptumRx that any such PBM payments are "not payment for prescription drugs." The Court thus concludes that EPPs' aggregate damages model is consistent with the exclusion of PBMs from class membership.

6. *Availability of Pass-On Defense Under State Law*

Defendants contend that individualized issues predominate because, unlike federal law, some states allow antitrust defendants to raise a pass-on defense, which requires individualized analysis as to whether any particular plaintiff sustained actual economic harm. Defs.' Opp'n Class Cert. 68–70. They rely on the opinion of their expert, John Fritz, to argue that many EPPs did not suffer actual economic harm because those EPPs passed on any overcharge incurred through increased insurance or contribution premiums. *Id*. at 72–75.

EPPs respond that the pass-on defense is not available under most state statutes, and when it is available, it is limited to transactions within the chain of distribution and does not include premium payments. EPPs' Reply Class Cert. 36. EPPs also filed a Motion to Exclude the Opinions and Testimony of Fritz.

As explained *supra*, to the extent that state laws do permit a pass-on defense,[11] that defense relates to the quantum of damages, not antitrust injury. Unlike antitrust injury, a "relaxed measure of proof" is applied to antitrust damages calculations and "the actual amount of damages may result from a 'reasonable estimate.'" *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1176 (3d Cir. 1993); *Eastman Kodak Co. of New York v. S. Photo Materials Co.*, 273 U.S. 359, 379 (1927) ("[A] defendant whose wrongful conduct has rendered

[11] EPPs have failed to provide to the Court with an adequate analysis of which state antitrust laws permit a pass-on defense to damages. EPPs summarily contend that the pass-on defense is not permitted under state law because "the relevant antitrust statutes have language mirroring federal antitrust laws, contain a federal harmonization provision, and/or have been interpreted in harmony with federal law." EPPs' Class Cert. Mot. 20 (citing App. A). However, as defendants persuasively argue, "[i]n permitting indirect purchaser actions at all, the [*Illinois Brick* repealer] state has already determined that its laws will not follow, but rather will deviate significantly, from federal antitrust law." Defs.' Opp'n Class Cert. 70; May 15, 2019 Hr'g Tr. 20:6–19. These statutory deviations specifically repeal *Illinois Brick*'s bar against indirect purchaser actions, the symmetrical counterpart to *Hanover Shoe* which eliminated the pass-on defense under federal law. *See In re Lower Lake Erie Iron Ore Antitrust Litig*., 998 F.2d 1144, 1164 n.10 (3d Cir. 1993). As such, EPPs' references to generic federal antitrust harmonization provisions does not provide the Court with the individualized analysis of the applicable states' laws to determine whether each state would permit a pass-on defense, and "the Court will decline to undertake the 'back-breaking labor involved in deciphering the state of antitrust [pass-on defense] in each of those states.'" *See In re Processed Egg Prod. Antitrust Litig*., 312 F.R.D. 124, 148–149 (E.D. Pa. 2015).

difficult the ascertainment of the precise damages suffered by the plaintiff, is not entitled to complain that they cannot be measured with the same exactness and precision as would otherwise be possible."). Any adjustment to damages calculations for pass-on defenses arising under state laws would not affect the fact of antitrust injury, and does not preclude class certification.

As a result, the availability of the pass-on defense involves "merits-related issues 'beyond what is necessary to determine preliminarily whether certain elements will necessitate individual or common proof.'" *See Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305 (3d Cir. 2016). Accordingly, the Court does not address defendants' argument that certain class members did not suffer actual economic harm based on the pass-on defense or EPPs' motion to exclude Fritz's opinion addressing that issue.

7. *Consumer Protection and Unfair Trade Practices Claims and Unjust Enrichment Claims*

EPPs assert that their claims arising under state consumer protection and unfair trade practices laws "all recognize that satisfaction of antitrust elements constitute liability." EPPs' Reply Class Cert. 2. EPPs have asserted no other theory of liability under the state consumer protection laws. Because the Court concludes that common issues do not predominate as to EPPs' antitrust claims, the Court likewise rejects EPPs' argument with respect to the state consumer protection claims. *See In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. 124, 163 (E.D. Pa. 2015).

EPPs also argue that "all invoked unjust enrichment claims include essentially the same equitable elements" as the antitrust claims. EPPs' Reply Class Cert. 2. However, because EPPs have failed to demonstrate that common issues predominate as to their antitrust claims, and because EPPs assert no other theory of unjust enrichment, the Court rejects EPPs' argument as to

EPPs' unjust enrichment claims. *See In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. at 163.

For these reasons, the Court concludes that EPPs' claims arising under consumer protection and unfair trade practices statutes and EPPs' unjust enrichment claims fail the Rule 23(b)(3) predominance requirement.

8. *Variations in States Laws*

Defendants further argue that the variations between the various state laws under which EPPs bring their claims defeat predominance.[12] Defs.' Opp'n Class Cert. 77–88.

EPPs' burden of demonstrating that common questions of law or fact predominate "includes providing the Court with an extensive analysis which demonstrates that the variations in the applicable state laws do not defeat predominance."[13] *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at *33 (E.D. Pa. June 10, 2015). Under the Third Circuit standard, courts may "certify nationwide classes where differences in state law f[a]ll 'into a limited number of predictable patterns,' and any deviations 'could be overcome at trial by grouping similar state laws together and applying them as a unit.'" *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014). However, "plaintiffs face a significant burden to demonstrate that grouping is a workable solution." *Id*; *see also In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *16 (D.N.J. Oct. 30, 2018) ("In a motion for class

[12] Defendants also claim that EPPs failed to properly conduct a choice of law analysis. Defs.' Opp'n Class Cert. 77–81. The Court is not persuaded by this argument and agrees with EPPs that "[u]nder proper choice of law principles, the law of the state where the drug was purchased from a pharmacy governs because the injury (i. e., overcharge) occurs at the point of sale." EPPs' Reply Class Cert. 54. *See In re Flonase Antitrust Litig.*, 815 F. Supp. 2d 867, 883-84 (E.D. Pa. 2011); *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 134–136 (E.D. Pa. 2011); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 391 (E.D. Pa. 2010).

[13] The inquiry into whether variations in state laws can be manageably addressed implicates both the predominance and superiority requirements. *See Vista Healthplan, Inc.*, No. 06-1833, 2015 WL 3623005, at *35. The Court considers this issue under the predominance standard. *See, e.g.*, *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *11.

certification, plaintiff bears the burden of providing an extensive analysis of state law variations to determine whether there are insuperable obstacles to class certification.").

Defendants contend that "[f]or this case to proceed as a class action, this Court would need to analyze the specific elements and issues that may arise under 53 state laws, decide critical and unsettled legal issues regarding how those laws would apply to the allegations in this case, and determine how the case will be adjudicated and tried under the 53 state laws." Defs.' Opp'n Class Cert. 77. They further assert that "EPPs provide no analysis of the state laws, no explanation of how they plan to prove the necessary elements of the 53 state laws, no proposed jury instructions nor any plan to address and manage these issues." *Id.*; May 15 Tr. 33:9–35:23. In addition, defendants raise numerous putative differences between the various state laws. Defs.' Opp'n Class Cert. 81–88.

EPPs reply that "'variations' in applicable state laws do not exist or are minor and manageable." EPPs' Reply Class Cert. 54. They assure the Court that any variations between the various statutes "can be handled via a special verdict form or by separating the purported variations into grouped categories." *Id*. at 58. They also note that some courts have held that differences between state consumer protection and unjust enrichment laws do not defeat predominance and address many of the alleged specific variations raised by defendants. *Id*. at 56–68.

The Court is not persuaded by EPPs' *ipse dixit* that there are no significant variations between the various state laws. The Third Circuit's *Grandalski* opinion is instructive in this regard. In that case, the plaintiffs "failed to provide a sufficient, or virtually any, analysis describing how the grouped state laws might apply to the facts of this case. They assert[ed] only that the differences between the state laws within each group are 'insignificant or non-existent.'"

Grandalski v. Quest Diagnostics Inc., 767 F.3d at 184. The *Grandalski* court explained that "[plaintiffs] must do more than provide their own *ipse dixit*, citation to a similar case, and a generic assessment of state consumer fraud statutes, to justify grouping." *Id.*

In this case, EPPs have provided no analysis of any variations between the various state laws other than to assure the Court that such differences are minor and manageable. Without an extensive analysis of the applicable state laws and any variation in state law, EPPs cannot meet their burden of proving predominance under Rule 23. *See Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *34 (E.D. Pa. June 10, 2015) (concluding that "Plaintiffs' accounting of the state variations [was] not comprehensive and glosses over important differences."); *see also In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. 124, 164 (E.D. Pa. 2015) ("Plaintiffs have provided charts seeking to demonstrate what the requirements of each state are with respect to the claims at issue[], but Plaintiffs have not proposed how those state claims would be grouped and managed at trial.").

Moreover, in other indirect purchaser antitrust actions proceeding under a wide array of state laws, plaintiffs have proposed trial plans, jury instructions or verdict sheets to assist the Court in understanding how any variations could be managed at trial. *See, e.g.*, *Vista Healthplan, Inc.*, No. 06-1833, 2015 WL 3623005, at *34 (evaluating plaintiffs' "proposed jury instructions [to] organize the state laws into a limited number of permutations"); *In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. at 165 (considering plaintiffs' "Suggested Trial Options" memorandum); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2017 WL 4621777, at *20 (D. Mass. Oct. 16, 2017) (addressing plaintiffs' proposed multiple phase trial plan). EPPs have not presented any such proposals in this case. Any renewed motion for class certification by EPPs should include, at minimum, charts identifying the substantive elements of each state

law claim, an analysis of all variations between the state law claims, and a proposed trial plan through which these variations may be manageably addressed.

For all of the above reasons, the Court concludes that EPPs have not satisfied the predominance requirement.

iii. Superiority

The superiority requirement "asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication." *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 533–34 (3d Cir. 2004). "[S]uperiority, unlike numerosity, considers alternatives to class actions other than joinder." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 253 n.11 (3d Cir. 2016).

In considering whether superiority is established, the Court must consider "whether variations in state laws present the types of insuperable obstacles which render class litigation unmanageable." *Vista Healthplan, Inc.*, No. 06-1833, 2015 WL 3623005, at *35 (citing *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 529 (3d Cir. 2004)). For the reasons stated above, EPPs have not provided a record sufficient for the Court to conclude that variations in applicable state laws are manageable in a single trial. They have not demonstrated by a preponderance of the evidence that a single class action proceeding under the 53 state laws arising from 26 jurisdictions would be superior to alternative available methods of adjudication. The Court thus concludes that EPPs have not established superiority on the current state of the record.

iv. Conclusion

In sum, EPPs have not satisfied their burden of establishing ascertainability, predominance, or superiority by a preponderance of the evidence. For these reasons, EPPs'

motion for class certification is denied. This decision is without prejudice to EPPs' right to file an amended motion for class certification if warranted by the facts and applicable law as set forth in this Memorandum.

V. EPPS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF JOHN F. FRITZ

EPPs filed a motion to exclude the opinions and testimony of defendants' expert witness, John Fritz, who opines that certain EPP class members passed on the costs of any overcharge and therefore did not sustain actual economic harm. Mem. L. Supp. EPPs' Mot. Exclude Opinions & Test. John F. Fritz 1. As explained above, the issue of whether recoverable damages are limited to a class members' actual economic harm does not impact class certification, and the Court need not address this issue at this stage in the litigation. In light of the Court's denial of EPPs' motion for class certification, EPP's motion to exclude Fritz's opinions and testimony is denied as moot. This decision is without prejudice to plaintiffs' right to challenge Fritz's expert testimony, if warranted, at a later stage in this litigation.

VI. CONCLUSION

For the reasons set forth above, (1) defendants' Motion to Exclude the Expert Testimony of Laura Craft and Eric Miller is denied, (2) EPPs' Motion for Class Certification is denied without prejudice to EPPs' right to file an amended motion if warranted by the facts and applicable law as set forth in this Memorandum, and (3) EPPs' Motion to Exclude the Opinions and Testimony of John F. Fritz is denied as moot.

An appropriate Order follows.